UNITED STATES CODE

1976 EDITION

CONTAINING THE GENERAL AND PERMANENT LAWS
OF THE UNITED STATES, IN FORCE
ON JANUARY 3, 1977

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VOLUME SIX

TITLE 21—FOOD AND DRUGS
TO
TITLE 25—INDIANS

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TITLES OF UNITED STATES CODE

*1. General Provisions.
2. The Congress.
*3. The President.
*4. Flag and Seal, Seat of Government, and the States.
*5. Government Organization and Employees.
*6. Surety Bonds.
7. Agriculture.
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*This title has been enacted as law.
†This title has been eliminated by the enactment of Title 10.

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PREFACE—1976 EDITION

This ninth edition of the United States Code was prepared and published pursuant to section 285b of Title 2 of the Code. It contains a consolidation and codification of all the general and permanent laws of the United States which are in force on January 3, 1977. By statutory authority this edition may be cited "U.S.C. 1976 ed." Previous editions were published in 1926, 1934, 1940, 1946, 1952, 1958, 1964, and 1970.

Inasmuch as many of the general and permanent laws which are required to be incorporated in this Code are inconsistent, redundant, and obsolete, the Office of the Law Revision Counsel is engaged in a comprehensive project of revising and enacting the Code into law, title by title. Since 1947, bills have been enacted to revise, codify and enact into law Titles 1, 3, 4, 5, 6, 9, 10, 13, 14, 17, 18, 23, 28, 32, 35, 37, 38, 39, and 44. In addition, bills relating to other titles are also being prepared for introduction. When this work is completed all the titles of the Code will be legal evidence of the general and permanent law and recourse to the numerous volumes of the Statutes at Large for this purpose will be unnecessary.

The title and chapter structure of the 1970 edition, together with Supplement V thereto, has been substantially preserved, the only changes made having been necessitated by the enactment of legislation since 1970.

This edition continues the practice of setting out notes captioned "Section referred to in other sections". These notes have been inserted following each section that is referred to in the text of another section, indicating the section that contains the internal reference. In addition, there is included in this edition, for the first time, a comprehensive Table of Internal References which appears in the Tables volume. This Table consolidates all internal references contained in the individual "Section referred to in other sections" notes.

This edition has been prepared and published under the supervision of Edward F. Willett, Jr., Law Revision Counsel of the House of Representatives, with the assistance of the West Publishing Company, of St. Paul, Minnesota, which assisted in preparing all prior editions and supplements of the Code. Grateful acknowledgment is made of the cooperation by all who have helped in this work, particularly by the staffs of the publishing company and of the Office of the Law Revision Counsel, and by the Government Printing Office.

Thomas P. O'Neill, Jr., M.C.

Speaker of the House of Representatives

WASHINGTON, D.C., *January 4, 1977.*

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CHAPTER 1—ADULTERATED OR MISBRANDED FOODS OR DRUGS

SUBCHAPTER I—FEDERAL FOOD AND DRUGS ACT OF 1906

Sec.
1 to 5. Repealed.
6. Transferred.
7 to 14. Repealed.
14a. Transferred.
15. Repealed.

SUBCHAPTER II—MISCELLANEOUS PROVISIONS

16. Introduction into, or sale in, State or Territory or District of Columbia of dairy or food products falsely labeled or branded.
17. Penalty for sale or introduction of falsely labeled dairy or food products; venue.
18. Suspension of importation of adulterated articles.
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20. Apples in interstate commerce; standard grades.
21. Branding grades on barrels.
22. Barrels misbranded.
23. Penalties.
24. Omitted.

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26. Omitted.

SUBCHAPTER I—FEDERAL FOOD AND DRUGS ACT OF 1906

§§ 1 to 5. Repealed. June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059

Section 1, act June 30, 1906, ch. 3915, § 1, 34 Stat. 768, made it unlawful to manufacture adulterated or misbranded foods or drugs in the Territories or the District of Columbia and provided penalty for violations. See sections 331 and 333 of this title.

Section 2, act June 30, 1906, ch. 3915, § 2, 34 Stat. 768, prohibited the introduction, shipment, delivery or sale of adulterated or misbranded foods or drugs in interstate or foreign commerce, provided penalty for violations and exempted exports conforming to specifications of foreign purchaser and not in conflict with laws of foreign country importing the same. See sections 331, 333 and 381 of this title.

Section 3, acts June 30, 1906, ch. 3915, § 3, 34 Stat. 768; Mar. 4, 1913, ch. 141, § 1, 37 Stat. 736, authorized the Secretaries of the Treasury, Agriculture and Commerce to make uniform rules and regulations for enforcement of food and drug laws, including collection and examination of specimens. See section 371 of this title.

Section 4, act June 30, 1906, ch. 3915, § 12, 34 Stat. 772, provided that act or omission of officer, agent, and so forth, of corporation, shall be deemed act or omission of corporation.

Section 5, act June 30, 1906, ch. 3915, § 12, 34 Stat. 772, defined "territory" and "person". See section 321 of this title and section 1 of Title 1, General Provisions.

EFFECTIVE DATE OF REPEAL

Section 902(a) of act June 25, 1938, ch. 675, 52 Stat. 1059, which repealed sections 1 to 5, 7 to 14, and 15 of this title, provided that the repeal of those sections should take effect upon the effective date of act June 25, 1938, which was to take effect twelve months after the date of its enactment. Act June 23, 1939, ch. 242, § 2(b), 53 Stat. 854, provided that: "The provisions of such act of June 30, 1906, as amended, to the extent that they impose, or authorize the imposition of, any requirement imposed by section 403(k) of the Federal Food, Drug, and Cosmetic Act (section 343(k) of this title), shall remain in force until January 1, 1940."

§ 6. Transferred

CODIFICATION

Section, act Mar. 4, 1923, ch. 268, 42 Stat. 1500, was transferred to section 321a of this title.

§§ 7 to 14. Repealed. June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059

Section 7, act June 30, 1906, ch. 3915, § 6, 34 Stat. 769, defined "drug" and "food." See section 321 of this title.

Section 8, act June 30, 1906, ch. 3915, § 7, 34 Stat. 769, deemed drugs to be adulterated when sold having a difference from recognized standards, except where there is an explanatory statement on or in container, and when sold below professed standard; confectioneries, when containing mineral substances, poisonous color or flavors, other deleterious ingredients, liquors or narcotics; food, when concerned with injurious mixtures, use of substitutes, abstraction of valuable constituents, concealment of damage or inferiority, deleterious ingredients, preservatives in shipment conditionally excepted, animal or vegetable substances unfit for food and products of animals diseased or having died otherwise than by slaughter. See sections 342 and 351 of this title.

Section 9, act June 30, 1906, ch. 3915, § 8, 34 Stat. 771, defined the term "misbranded" and provided for its application to drugs and food. See sections 343 and 352 of this title.

Section 10, acts June 30, 1906, ch. 3915, § 8, 34 Stat. 771; Aug. 23, 1912, ch. 352, 37 Stat. 416; Mar. 3, 1913, ch. 117, 37 Stat. 732; July 24, 1919, ch. 26, 41 Stat. 271; July 8, 1930, ch. 874, 46 Stat. 1019, deemed drugs to be misbranded when there is an imitation or use of name of other article, when there is removal and substitution of contents of package or failure to state on label quantity or proportion of narcotics therein, and when there is a false statement of curative or therapeutic effect; and food, when there is an imitation or use of name of other article, when there is a false label or brand removal and substitution of contents of package, or failure to state or label quantity or proportion of narcotics therein, when the packages are not marked with weight, with certain variations and exemptions permitted, when there are false or misleading statements on package or label as to ingredients or substances; and food, when mixtures or compounds under distinctive names, the articles are labeled, branded as compounds, imitations, or blends; construed the term "blend" and related to disclosure of trade formulas of proprietary foods, and canned food. See sections 321b, 341, 343 and 352 of this title.

Section 11, acts June 30, 1906, ch. 3915, § 4, 34 Stat. 769; Jan. 18, 1927, ch. 39, 44 Stat. 1003, provided for examination of specimens, notice of adulteration or misbranding, hearing, certification of violations to United States district attorney and notice of judgment.

Section 12, act June 30, 1906, ch. 3915, § 5, 34 Stat. 769, provided for prosecution by district attorneys for enforcement of penalties.

Section 13, act June 30, 1906, ch. 3915, § 9, 34 Stat. 771, provided for a seller's guaranty as protection to dealer. See section 333 of this title.

Section 14, act June 30, 1906, ch. 3915, § 10, 34 Stat. 771, provided for seizure of articles by libel for condemnation, at suit of and in name of United States, in United States district court where found, conforming to proceedings in admiralty, with right to trial by jury, destruction or sale of adulterated or misbranded articles, bond and payment of proceeds into Treasury of United States. See sections 332, 334 and 337 of this title.

EFFECTIVE DATE OF REPEAL

For effective date of repeal, see section 902(a) of act June 25, 1938, set out as an Effective Date of Repeal note under sections 1 to 5 of this title.

§ 14a. Transferred

CODIFICATION

Section, act June 30, 1906, ch. 3915, § 10A, as added June 22, 1934, ch. 712, 48 Stat. 1204, and amended Aug. 27, 1935, ch. 739, 49 Stat. 871, which related to the examination of sea food on request of the packer, the marking of food with the results, fees, and penalties, was transferred to section 372a of this title.

§ 15. Repealed. June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059

Section, act June 30, 1906, ch. 3915, § 11, 34 Stat. 772, provided for examination of samples of imports, refusal of admission and delivery to consignee, delivery to consignee pending examination and decision on bond and charges for storage and lien therefor. See section 381 of this title.

EFFECTIVE DATE OF REPEAL

For effective date of repeal, see section 902(a) of act June 25, 1938, set out as an Effective Date of Repeal note under sections 1 to 5 of this title.

SUBCHAPTER II—MISCELLANEOUS PROVISIONS

§ 16. Introduction into, or sale in, State or Territory or District of Columbia of dairy or food products falsely labeled or branded

No person or persons, company or corporation, shall introduce into any State or Territory of the United States or the District of Columbia from any other State or Territory of the United States or the District of Columbia, or sell in the District of Columbia or in any Territory any dairy or food products which shall be falsely labeled or branded as to the State or Territory in which they are made, produced, or grown, or cause or procure the same to be done by others.

(July 1, 1902, ch. 1357, § 1, 32 Stat. 632.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 17 of this title.

§ 17. Penalty for sale or introduction of falsely labeled dairy or food products; venue

If any person or persons violate the provisions of section 16 of this title, either in person or through another, he shall be guilty of a misdemeanor and shall be punished by a fine of not less than $500 nor more than $2,000. The jurisdiction for the prosecution of said misdemeanor shall be within the district of the United States court in which it is committed.

(July 1, 1902, ch. 1357, § 2, 32 Stat. 632.)

FEDERAL RULES OF CRIMINAL PROCEDURE

Continuance of section under rule 18, see note by Advisory Committee under rule 18, Title 18, Appendix, Crimes and Criminal Procedure.

§ 18. Suspension of importation of adulterated articles

Whenever the President is satisfied that there is good reason to believe that any importation is being made, or is about to be made, into the United States, from any foreign country, of any article used for human food or drink that is adulterated to an extent dangerous to the health or welfare of the people of the United States, or any of them, he may issue his proclamation suspending the importation of such articles from such country for such period of time as he may think necessary to prevent such importation; and during such period it shall be unlawful to import into the United States from the countries designated in the proclamation of the President any of the articles the importation of which is so suspended.

(Aug. 30, 1890, ch. 839, § 4, 26 Stat. 415.)

§ 19. Repealed. May 29, 1928, ch. 901, § 1(100), 45 Stat. 993

Section, act May 23, 1908, ch. 192, 35 Stat. 261, related to report to the Congress of expenditures in enforcing food and drug laws.

§ 20. Apples in interstate commerce; standard grades

The standard grades for apples when packed in barrels which shall be shipped or delivered for shipment in interstate or foreign commerce, or which shall be sold or offered for sale within the District of Columbia or the Territories of the United States shall be as follows: Apples of one variety, which are well-grown specimens, hand picked, of good color for the variety, normal shape, practically free from insect and fungous injury, bruises, and other defects, except such as are necessarily caused in the operation of packing, or apples of one variety which are not more than 10 per centum below the foregoing specifications shall be "Standard grade minimum size two and one-half inches", if the minimum size of the apples is two and one-half inches in transverse diameter; "Standard grade minimum size two and one-fourth inches", if the minimum size of the apples is two and one-fourth inches in transverse diameter; or "Standard grade minimum size two inches", if the minimum size of the apples is two inches in transverse diameter.

(Aug. 3, 1912, ch. 273, § 2, 37 Stat. 250.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 21, 22, 23 of this title.

§ 21. Branding grades on barrels of apples

The barrels in which apples are packed in accordance with the provisions of sections 20 to 23 of this title may be branded in accordance with the provisions of section 20 of this title.

(Aug. 3, 1912, ch. 273, § 3, 37 Stat. 251.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 22, 23 of this title.

§ 22. Barrels misbranded

Barrels packed with apples shall be deemed to be misbranded within the meaning of sections 20 to 23 of this title—

First. If the barrel bears any statement, design, or device indicating that the apples contained therein are "Standard" grade and the apples when packed do not conform to the requirements prescribed by section 20 of this title.

Second. If the barrel bears any statement, design, or device indicating that the apples contained therein are "Standard" grade and the barrel fails to bear also a statement of the name of the variety, the name of the locality where grown, and the name of the packer or the person by whose authority the apples were packed and the barrel marked.

(Aug. 3, 1912, ch. 273, § 5, 37 Stat. 251.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 21, 23 of this title.

§ 23. Penalties

Any person, firm or corporation, or association who shall knowingly pack or cause to be packed apples in barrels or who shall knowingly sell or offer for sale such barrels in violation of the provisions of sections 20 to 23 of this title shall be liable to a penalty of $1 and costs for each such barrel so sold or offered for sale, to be recovered at the suit of the United States in any court of the United States having jurisdiction.

(Aug. 3, 1912, ch. 273, § 6, 37 Stat. 251.)

CODIFICATION

Section is also set out as section 233 of Title 15, Commerce and Trade.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 21, 22 of this title.

§ 24. Omitted

CODIFICATION

Section, act Mar. 4, 1915, ch. 144, 38 Stat. 1102, has been omitted as obsolete. It related to payment of the cost of inspection under a provision authorizing the investigation of the character of chemical and physical tests applied to American food products in foreign countries and the inspection of such products before shipment to such countries at the request of the shippers or owners. That provision was repeated in subsequent appropriation acts but was omitted from the appropriation act of July 12, 1943, ch. 221, 57 Stat. 494, and from all subsequent appropriation acts.

§ 25. Oleomargarine, butterine, or imitation butter or cheese transported into a State subject to its police powers

All articles known as oleomargarine, butterine, imitation, process, renovated, or adulterated butter, or imitation cheese, or any substance in the semblance of butter or cheese not the usual product of the dairy and not made exclusively of pure and unadulterated milk or cream, transported into any State or Territory or the District of Columbia, and remaining therein for use, consumption, sale, or storage therein, shall, upon the arrival within the limits of such State or Territory or the District of Columbia, be subject to the operation and effect of the laws of such State or Territory or the District of Columbia, enacted in the exercise of its police powers to the same extent and in the same manner as though such articles or substances had been produced in such State or Territory or the District of Columbia, and shall not be exempt therefrom by reason of being introduced therein in original packages or otherwise.

(May 9, 1902, ch. 784, § 1, 32 Stat. 193.)

CROSS REFERENCES

Colored oleomargarine, intrastate sales of, see section 347 et seq. of this title.

§ 26. Omitted

CODIFICATION

Section, which was from the appropriation acts of Jan. 18, 1927, ch. 39, 44 Stat. 984; May 16, 1928, ch. 572, 45 Stat. 548; Feb. 16, 1929, ch. 227, 45 Stat. 1198; May 27, 1930, ch. 341, 46 Stat. 424, and subsequent Department of Agriculture Appropriation Acts to and in-

cluding act June 28, 1944, ch. 296, § 4, 58 Stat. 461, is now covered by section 2256 of Title 7, Agriculture.

CHAPTER 2—TEAS

Sec.
41. Importation of tea inferior to standard.
42. Board of experts; appointment; term; vacancies; compensation.
43. Standards of purity; duplicate samples at customhouses and for importers and dealers.
44. Bonds of importers; examination; importations at ports having no examiner.
45. Permit for delivery; retention of inferior grades; reexamination; partial delivery.
46. Examiners; examination according to usages of trade.
46a. Deposit of fee before examination of tea.
47. United States Board of Tea Appeals; permit for delivery; exportation or destruction of inferior grades.
48. Reexamination; findings by examiner; assistance of experts.
49. Reimporting rejected teas; forfeiture.
50. Regulations.

§ 41. Importation of tea inferior to standard

It shall be unlawful for any person or persons or corporation to import or bring into the United States any merchandise as tea which is inferior in purity, quality, and fitness for consumption to the standards provided in section 43 of this title, and the importation of all such merchandise is prohibited, except as provided in the Tariff Schedules of the United States.

(Mar. 2, 1897, ch. 358, § 1, 29 Stat. 604; May 16, 1908, ch. 170, 35 Stat. 163; May 31, 1920, ch. 217, 41 Stat. 712; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; May 24, 1962, Pub. L. 87-456, title III, § 303(a), 76 Stat. 77.)

References in Text

The Tariff Schedules of the United States, referred to in text, are set out in section 1202 of Title 19, Customs Duties.

Amendments

1962—Pub. L. 87-456 inserted words "except as provided in the Tariff Schedules of the United States" at the end of the first sentence, and deleted the second sentence which related to the importation under bond of tea inferior to standards, tea waste, tea siftings, or tea sweepings, under regulations prescribed by the Secretary of the Treasury, for the sole purpose of manufacturing theine, caffeine, or other chemical products whereby the identity and character of the original material is entirely destroyed or changed and that the bonds shall be subject to the approval only of the collector of customs at the port of entry. See Revised Tariff Schedules set out in section 1202 of Title 19, Customs Duties.

Effective Date of 1962 Amendment

Amendment by Pub. L. 87-456 effective with respect to articles entered, or withdrawn from warehouse, for consumption on or after Aug. 31, 1963, see section 501(a) of Pub. L. 87-456, set out as a note preceding section 1202 of Title 19, Customs Duties.

Short Title

Act July 12, 1943, ch. 221, title II, 57 Stat. 499, provided in part that act Mar. 2, 1897, which is classified to sections 41 to 46, and 47 to 50 of this title may be cited as the "Tea Importation Act".

Transfer of Functions

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out in the Appendix to Title 5, Government Organization and Employees. The Federal Security Agency and the office of Administrator was abolished by section 8 of Reorg. Plan No. 1 of 1953.

The Food and Drug Administration in the Department of Agriculture and its functions, except those functions relating to the administration of the Insecticide Act of 1910 and the Naval Stores Act, were transferred to the Federal Security Agency, to be administered under the direction and supervision of the Federal Security Administrator, by Reorg. Plan No. IV of 1940, set out in the Appendix to title 5.

The powers and duties of the Secretary of the Treasury under this section were conferred upon the Secretary of Agriculture by act May 31, 1920.

Section Referred to in Other Sections

This section is referred to in sections 43, 45 of this title.

§ 42. Board of exports; appointment; term; vacancies; compensation

On or before February 15 of each year, the Secretary of Health, Education, and Welfare shall appoint a board, to consist of seven members, each of whom shall be an expert in teas, and who shall prepare and submit to him standard samples of tea. The persons so appointed shall be at all times subject to removal by the said Secretary, and shall serve for the term of one year. Vacancies in the said board occurring by removal, death, resignation, or any other cause shall be forthwith filled by the Secretary of Health, Education, and Welfare by appointment, such appointee to hold for the unexpired term. Said board shall appoint a presiding officer, who shall be the medium of all communications to or from such board. Each member of said board shall receive as compensation the sum of $50 per annum, which, together with all necessary expenses while engaged upon the duty herein provided, shall be paid by the Secretary.

(Mar. 2, 1897, ch. 358, § 2, 29 Stat. 605; May 31, 1920, ch. 217, 41 Stat. 712; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; July 12, 1943, ch. 221, title II, § 201, 57 Stat. 500; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

Amendments

1943—Act July 12, 1943, provided that the Administrator should pay the salaries and expenses of the Board members.

Transfer of Functions

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions notes set out under section 41 of this title.

Section Referred to in Other Sections

This section is referred to in sections 43, 45 of this title.

§ 43. Standards of purity; duplicate samples at customhouses and for importers and dealers

The Secretary of Health, Education, and Welfare, upon the recommendation of the board of experts provided in section 42 of this title, shall fix and establish uniform standards of purity, quality, and fitness for consumption of all kinds of teas imported into the United States, and shall procure and deposit in the customhouses of the ports of New York, Chicago, San Francisco, and such other ports as he may determine, duplicate samples of such standards. Said Secretary shall procure a sufficient number of other duplicate samples of such standards to supply the importers and dealers in tea at all ports desiring the same at cost. All teas, or merchandise described as tea, of inferior purity, quality, and fitness for consumption to such standards shall be deemed within the prohibition of section 41 of this title.

(Mar. 2, 1897, ch. 358, § 3, 29 Stat. 605; May 31, 1920, ch. 217, 41 Stat. 712; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions notes set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 41, 45 of this title.

§ 44. Bonds of importers; examination; importations at ports having no examiner

On making entry at the customhouse of all teas, or merchandise described as tea, imported into the United States, the importer or consignee shall give a bond to the collector of the port that such merchandise shall not be removed from the warehouse until released by the collector, after it shall have been duly examined with reference to its purity, quality, and fitness for consumption. For the purpose of such examination samples of each line in every invoice of tea shall be submitted by the importer or consignee to the examiner, together with the sworn statement of such importer or consignee that such samples represent the true quality of each and every part of the invoice and accord with the specifications therein contained; or in the discretion of the Secretary of Health, Education, and Welfare, such samples shall be obtained by the examiner and compared by him with the standards established by this chapter. In cases where said tea, or merchandise described as tea, is entered at ports where there is no qualified examiner as provided in section 46 of this title, the consignee or importer shall in the manner aforesaid furnish under oath a sample of each line of tea to the collector or other revenue officer to whom is committed the collection of duties, and said officer shall also draw or cause to be drawn samples of each line in every invoice and shall forward the same to a duly qualified examiner as provided in said section. The bond required by this section shall also be conditioned for the payment of all customhouse charges which may attach to such merchandise prior to its being released or destroyed (as the case may be) under the provisions of this chapter.

(Mar. 2, 1897, ch. 358, § 4, 29 Stat. 605; May 31, 1920, ch. 217, 41 Stat. 712; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions notes set out under section 41 of this title.

All offices of collector of customs in the Bureau of Customs of the Department of the Treasury were ordered abolished, with such offices to be terminated not later than Dec. 31, 1966, by Reorg. Plan No. 1 of 1965, eff. May 25, 1965, 30 F.R. 7035, 79 Stat. 1317, set out in the Appendix to Title 5, Government Organization and Employees. All functions of the offices eliminated were already vested in the Secretary of the Treasury by Reorg. Plan No. 26 of 1950, eff. July 31, 1950, 15 F.R. 4935, 64 Stat. 1280, also set out in the Appendix to title 5.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 45, 46 of this title.

§ 45. Permit for delivery; retention of inferior grades; reexamination; partial delivery

If, after an examination as provided in section 44 of this title, the tea is found by the examiner to be equal in purity, quality, and fitness for consumption to the standards provided in sections 41 to 44 of this title, and no reexamination shall be demanded by the collector as provided in section 47 of this title, a permit shall at once be granted to the importer or consignee declaring the tea free from the control of the customs authorities; but if on examination such tea, or merchandise described as tea, is found, in the opinion of the examiner, to be inferior in purity, quality, and fitness for consumption to the said standards the importer or consignee shall be immediately notified, and the tea, or merchandise described as tea, shall not be released by the customhouse, unless on a reexamination called for by the importer or consignee the finding of the examiner shall be found to be erroneous. Should a portion of the invoice be passed by the examiner, a permit shall be granted for that portion and the remainder held for further examination, as provided in said section 47.

(Mar. 2, 1897, ch. 358, § 5, 29 Stat. 605.)

TRANSFER OF FUNCTIONS

For abolition of the offices of collector of customs, see Transfer of Functions note set out under section 44 of this title.

§ 46. Examiners; examination according to usages of trade

The examination provided for by this chapter shall be made by a duly qualified examiner at a port where standard samples are established, and where the merchandise is entered at ports where there is no qualified examiner, the examination shall be made at that one of said

ports which is nearest the port of entry, and that for this purpose samples of the merchandise, obtained in the manner prescribed by section 44 of this title, shall be forwarded to the proper port by the collector or chief officer at the port of entry. In all cases of examination or reexamination of teas, or merchandise described as tea, by examiners or the United States Board of Tea Appeals under the provisions of this chapter, the purity, quality, and fitness for consumption of the same shall be tested according to the usages and customs of the tea trade, including the testing of an infusion of the same in boiling water and, if necessary, chemical analysis.

(Mar. 2, 1897, ch. 358, § 7, 29 Stat. 606; May 31, 1920, ch. 217, 41 Stat. 712, 713.)

TRANSFER OF FUNCTIONS

For abolition of the offices of collector of customs, see Transfer of Functions note set out under section 44 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 44 of this title.

§ 46a. Deposit of fee before examination of tea

On and after July 1, 1940, no tea, or merchandise described as tea, shall be examined for importation into the United States, or released by the Collector, under this chapter unless the importer or consignee of such tea or merchandise, prior to such examination, has paid for deposit into the Treasury of the United States as miscellaneous receipts, a fee of 3.5 cents for each hundred weight or fraction thereof of such tea and merchandise.

(June 27, 1940, ch. 437, title I, 54 Stat. 632; July 1, 1941, ch. 269, title II, 55 Stat. 478.)

CODIFICATION

Section was not enacted as part of act Mar. 2, 1897, ch. 358, 29 Stat. 604, which comprises this chapter.

AMENDMENTS

1941—Act July 1, 1941, reenacted section without change.

TRANSFER OF FUNCTIONS

For abolition of the offices of collector of customs, see Transfer of Functions note set out under section 44 of this title.

§ 47. United States Board of Tea Appeals; permit for delivery; exportation or destruction of inferior grades

In case the collector, importer, or consignee shall protest against the finding of the examiner, the matter in dispute shall be referred for decision to the United States Board of Tea Appeals, to consist of three employees of the Department of Health, Education, and Welfare, to be designated by the Secretary of Health, Education, and Welfare. If such board shall, after due examination, find the tea in question to be equal in purity, quality, and fitness for consumption to the proper standards, a permit shall be issued by the collector for its release and delivery to the importer; but if upon such final reexamination by such board the tea shall be found to be inferior in purity, quality, and fitness for consumption to the said standards, the importer or consignee shall give a bond, with security satisfactory to the collector, to export said tea, or merchandise described as tea, out of the limits of the United States within a period of six months after such final reexamination; and if the same shall not have been exported within the time specified, the collector, at the expiration of that time, shall cause the same to be destroyed.

(Mar. 2, 1897, ch. 358, § 6, 29 Stat. 606; May 31, 1920, ch. 217, 41 Stat. 712, 713; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions notes set out under section 41 of this title.

For abolition of the offices of the collector of customs, see Transfer of Functions note set out under section 44 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 45 of this title.

§ 48. Reexamination; findings by examiner; assistance of experts

In cases of reexamination of teas, or merchandise described as teas, by the United States Board of Tea Appeals in pursuance of the provisions of this chapter, samples of the tea, or merchandise described as tea, in dispute, for transmission to such board for its decision, shall be put up and sealed by the examiner in the presence of the importer or consignee if he so desires, and transmitted to such board, together with a copy of the finding of the examiner, setting forth the cause of condemnation and the claim or ground of the protest of the importer relating to the same, such samples, and the papers therewith, to be distinguished by such mark that the same may be identified. The decision of such board shall be in writing, signed by them, and transmitted, together with the record and samples, within three days after the rendition thereof, to the collector, who shall forthwith furnish the examiner and the importer or consignee with a copy of said decision or finding. The United States Board of Tea Appeals shall be authorized to obtain the advice, when necessary, of persons skilled in the examination of teas, who shall each receive for his services in any particular case a compensation not exceeding $5.

(Mar. 2, 1897, ch. 358, § 8, 29 Stat. 606; May 31, 1920, ch. 217, 41 Stat. 712.)

TRANSFER OF FUNCTIONS

For abolition of the offices of the collector of customs, see Transfer of Functions note set out under section 44 of this title.

§ 49. Reimporting rejected teas; forfeiture

No imported teas which have been rejected by a customs examiner or by the United States Board of Tea Appeals, and exported under the provisions of this chapter, shall be reimported into the United States under the penalty of forfeiture for a violation of this prohibition.

(Mar. 2, 1897, ch. 358, § 9, 29 Stat. 606; May 31, 1920, ch. 217, 41 Stat. 712.)

§ 50. Regulations

The Secretary of Health, Education, and Welfare shall have the power to enforce the provisions of this chapter by appropriate regulations.

(Mar. 2, 1897, ch. 358, § 10, 29 Stat. 607; May 31, 1920, ch. 217, 41 Stat. 712; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions notes set out under section 41 of this title.

CHAPTER 3—FILLED MILK

Sec.
61. Definitions.
62. Manufacture, shipment, or delivery for shipment in interstate or foreign commerce prohibited.
63. Penalties; acts of agents deemed acts of principals.
64. Regulations for enforcement.

FEDERAL FOOD, DRUG, AND COSMETIC ACT

By virtue of act June 25, 1938, ch. 675, § 902(c), 52 Stat. 1059 [section 392(b) of this title], nothing contained in section 301 et seq. of this title shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of sections 61 to 64 of this title.

BUREAU OF DAIRY INDUSTRY

General provisions, see sections 401 to 404 of Title 7, Agriculture.

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in section 392 of this title.

§ 61. Definitions

Whenever used in this chapter—

(a) The term "person" includes an individual partnership, corporation, or association;

(b) The term "interstate or foreign commerce" means commerce (1) between any State, Territory, or possession, or the District of Columbia, and any place outside thereof; (2) between points within the same State, Territory, or possession, or within the District of Columbia, but through any place outside thereof; or (3) within any Territory or possession, or within the District of Columbia; and

(c) The term "filled milk" means any milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated, to which has been added, or which has been blended or compounded with, any fat or oil other than milk fat, so that the resulting product is in imitation or semblance of milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated. This definition shall not include any distinctive proprietary food compound not readily mistaken in taste for milk or cream or for evaporated, condensed, or powdered milk, or cream where such compound (1) is prepared and designed for feeding infants and young children and customarily used on the order of a physician; (2) is packed in individual cans containing not more than sixteen and one-half ounces and bearing a label in bold type that the content is to be used only for said purpose; (3) is shipped in interstate or foreign commerce exclusively to physicians, wholesale and retail druggists, orphan asylums, child-welfare associations, hospitals, and similar institutions and generally disposed of by them.

(Mar. 4, 1923, ch. 262, § 1, 42 Stat. 1486.)

SHORT TITLE

Act July 12, 1943, ch. 221, title II, 57 Stat. 499, provided in part that act Mar. 4, 1923, which enacted this chapter, may be cited as the "Filled Milk Act".

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 62 of this title.

§ 62. Manufacture, shipment, or delivery for shipment in interstate or foreign commerce prohibited

It is declared that filled milk, as defined in section 61 of this title, is an adulterated article of food, injurious to the public health, and its sale constitutes a fraud upon the public. It shall be unlawful for any person to manufacture within any Territory or possession, or within the District of Columbia, or to ship or deliver for shipment in interstate or foreign commerce, any filled milk.

(Mar. 4, 1923, ch. 262, § 2, 42 Stat. 1487.)

§ 63. Penalties; acts of agents deemed acts of principals

Any person violating any provision of this chapter shall upon conviction thereof be subject to a fine of not more than $1,000 or imprisonment of not more than one year, or both. When construing and enforcing the provisions of this chapter, the act, omission, or failure of any person acting for or employed by any individual, partnership, corporation, or association, within the scope of his employment or office, shall in every case be deemed the act, omission, or failure, of such individual, partnership, corporation, or association, as well as of such person.

(Mar. 4, 1923, ch. 262, § 3, 42 Stat. 1487.)

CODIFICATION

The original text of this section contained a further provision that no penalty should be enforced for any violation occurring within 30 days after act Mar. 4, 1923 became law and was omitted as temporary and obsolete.

§ 64. Regulations for enforcement

The Secretary of Health, Education, and Welfare is authorized and directed to make and enforce such regulations as may in his judgment be necessary to carry out the purposes of this chapter.

(Mar. 4, 1923, ch. 262, § 4, as added Aug. 27, 1935, ch. 743, 49 Stat. 885; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions notes set out under section 41 of this title.

CHAPTER 4—ANIMALS, MEATS, AND MEAT AND DAIRY PRODUCTS

SUBCHAPTER I—EXAMINATION OF ANIMALS, MEATS, AND MEAT AND DAIRY PRODUCTS

Sec.
71 to 92. Transferred.
93. Repealed.
94 to 95. Transferred.
96. Repealed.
97 to 97d. Omitted.
98. Transferred.
99. Repealed.

SUBCHAPTER II—IMPORTATION OF CATTLE AND QUARANTINE

101. Suspension of importation of all animals.
102. Quarantine of imported animals.
103. Importation, except at quarantine ports, prohibited; slaughter of infected animals; appraisal; payment.
104. Importation of diseased animals prohibited; exception.
105. Inspection of animals imported or intended for export.
106, 107. Omitted.

SUBCHAPTER III—PREVENTION OF INTRODUCTION AND SPREAD OF CONTAGION

111. Regulations to prevent contagious diseases.
112. Investigations as to pleuropneumonia, and other diseases; regulations.
112a. Omitted.
113. Measures to prevent exportation of diseased livestock and live poultry.
113a. Establishment of research laboratories for foot-and-mouth disease and other animal diseases; research contracts; employment of technicians and scientists; appropriations.
114. Regulations for suppression of diseases; cooperation of States and Territories.
114a. Control and eradication of diseases; cooperation of States and farmers' associations; purchase and destruction of diseased animals; definition of State.
114a-1. Interstate movement of domestic animals reacting to tests for brucellosis; immediate slaughter; rules and regulations.
114b. Cooperation with Western Hemisphere countries in animal disease control.
114c. Use of funds for purchase or hire of vehicles and airplanes, printing, and employment of personnel.
114d. Repealed.
114d-1. Cooperation with public and private organizations and individuals in control and eradication of foot-and-mouth disease, rinderpest, and screw-worm.
114d-2 to 114d-6. Repealed.
114e. Control and eradication of cattle grubs; research and investigations.
114f. Definitions; authorization of appropriations.
114g. Hog cholera eradication program.
114h. Advisory committee.
(a) Establishment; membership.
(b) Functions.
(c) Employment status; expenses.
115. Transportation of diseased livestock and live poultry prohibited.
116. Shipment of certain cattle excepted.
117. Notice of existence of contagion to railroads; transportation of diseased stock or live poultry; penalty.
118. Duty of United States attorneys.
119. Agents to examine and report on methods of treatment of animals, and means for suppression of diseases.
120. Regulation of exportation and transportation of infected livestock and live poultry.
121. Shipments from areas suspected infected; control of animals and live poultry.
122. Offenses; penalty.
123. Quarantine.
124. Transportation or delivery therefor from quarantined State or Territory or portion thereof, of quarantined animals and live poultry, forbidden.
125. Regulations for inspection, disinfection, and certification, and delivery and shipment of quarantined animals and live poultry from State or Territory.
126. Moving quarantined animals and live poultry from State or Territory, under regulations.
127. Transportation from quarantined State, Territory, etc.; penalty.
128. Extension of quarantine law to carriers in interstate commerce.
129. Expenses for arrest and eradication of contagious or infectious diseases of animals; transfer of appropriations.
130. Pleuropneumonia in District of Columbia; duties of Council of the District of Columbia.
131. Fences along international boundary lines to keep out diseased animals.
132. Transferred.
133. Repealed.
134. Definitions.
134a. Seizure, quarantine, and disposal of livestock or poultry to guard against introduction or dissemination of communicable disease.
(a) Authority of Secretary.
(b) Determination of extraordinary emergency due to dangerous communicable disease; seizure, quarantine, and disposal of animals; action authorized only if adequate measures not taken by State or other jurisdiction; notice to State or other jurisdiction.
(c) Notice to owner to quarantine or to dispose of animal, carcass, product, or article; action on failure to comply; costs.
(d) Compensation of owner; fair market value; payments from State or other source; availability of funds.
(e) Restriction on payment of compensation in cases of violation of law or regulation.
134b. Regulations for clean and sanitary movement of animals.
134c. Regulations for movement of animals affected or exposed to communicable disease.
134d. Inspections and seizures; issuance of warrants.
134e. Penalties; enforcement provisions.
134f. Promulgation of regulations.
134g. Authority in addition to other laws; repeal of inconsistent provisions.
134h. Separability of provisions.
135. International animal quarantine station; establishment; acceptance of gifts; cooperation with breeders' organizations; collection of fees.
135a. Smuggling penalties.
135b. Authorization of appropriations.

SUBCHAPTER IV—IMPORTATION OF MILK AND CREAM

141. Prohibition of importation without permit.
142. Milk or cream when unfit for importation.

Sec.
143. Inspection; certified statement in lieu thereof; waiver of requirements of section 142; regulations; suspension and revocation of permits.
144. Unlawful receiving of imported milk or cream.
145. Penalties.
146. Authorization of appropriations.
147. Repeal of inconsistent laws.
148. Powers of State with respect of milk or cream lawfully imported.
149. Definitions; "person"; "United States."

SUBCHAPTER I—EXAMINATION OF ANIMALS, MEATS, AND MEAT AND DAIRY PRODUCTS

§§ 71 to 92. Transferred

CODIFICATION

Section 71, act Mar. 4, 1907, ch. 2907, 34 Stat. 1260, which related to inspection of meat and meat food products, examination of cattle before slaughtering, separate slaughtering of diseased animals and examination of carcasses, was transferred to section 603 of this title.

Section 72, act Mar. 4, 1907, ch. 2907, 34 Stat. 1260, which related to post mortem examination of carcasses, marking and labeling, destruction of condemned carcasses, and reinspection, was transferred to section 604 of this title.

Section 73, act Mar. 4, 1907, ch. 2907, 34 Stat. 1261, which related to examination of carcasses brought into slaughtering or packing establishments and of meat food products issued from and returned thereto, was transferred to section 605 of this title.

Section 74, act Mar. 4, 1907, ch. 2907, 34 Stat. 1261, which related to examination and inspection of meat food products, marks of inspection, destruction of condemned products, and products for export, was transferred to section 606 of this title.

Section 75, act Mar. 4, 1907, ch. 2907, 34 Stat. 1262, which related to labeling of receptacles and coverings of meat and meat food products inspected and passed, supervision by inspectors, prohibition of sales under false names, was transferred to section 607 of this title.

Section 76, act Mar. 4, 1907, ch. 2907, 34 Stat. 1262, which related to sanitary inspection and regulation of slaughtering and packing establishments, and rejection of meat or meat food products unfit for food, was transferred to section 608 of this title.

Section 77, act Mar. 4, 1907, ch. 2907, 34 Stat. 1262, which related to examination of cattle and food products thereof slaughtered and prepared during night time, was transferred to section 609 of this title.

Section 78, act Mar. 4, 1907, ch. 2907, 34 Stat. 1262, which related to prohibition of transportation of carcasses, meat, or meat food products not properly inspected and marked, was transferred to section 610 of this title.

Section 79, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to forgery, alteration, and unauthorized use of marks, labels, and certificates, was transferred to section 611 of this title.

Section 80, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to inspection of animals for export, was transferred to section 612 of this title.

Section 81, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to certificates of condition of animals for export, was transferred to section 613 of this title.

Section 82, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to clearance to vessels carrying cattle for export with proper certificate of inspection, was transferred to section 614 of this title.

Section 83, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to inspection of carcasses, the meat of which is intended for export, was transferred to section 615 of this title.

Section 84, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to certificates of condition of carcasses, the meat of which is intended for export, was transferred to section 616 of this title.

Section 85, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to clearance to vessels carrying meat for export with proper certificate of inspection, was transferred to section 617 of this title.

Section 86, act Mar. 4, 1907, ch. 2907, 34 Stat. 1263, which related to official certificates of inspection and delivery of copies thereof to different parties, was transferred to section 618 of this title.

Section 87, act Mar. 4, 1907, ch. 2907, 34 Stat. 1264, which related to prohibition of transportation or sale of meat or meat food products without complying with provisions of inspection law, was transferred to section 619 of this title.

Section 88, act Mar. 4, 1907, ch. 2907, 34 Stat. 1264, which related to offenses and penalties, was transferred to section 620 of this title.

Section 89, act Mar. 4, 1907, ch. 2907, 34 Stat. 1264, which related to appointment of inspectors, their duties, and rule making authority of the Secretary of Agriculture, was transferred to section 621 of this title.

Section 90, act Mar. 4, 1907, ch. 2907, 34 Stat. 1264, which related to penalties for bribery, was transferred to section 622 of this title.

Section 91, acts Mar. 4, 1907, ch. 2907, 34 Stat. 1265; June 29, 1938, ch. 810, 52 Stat. 1235, which related to definitions, exceptions to inspection requirements in case of farmers and retailers, and penalties for sale of meat and meat food products unfit for food, was transferred to section 623 of this title.

Section 92, act Mar. 4, 1907, ch. 2907, 34 Stat. 1265, which was a proviso following the first sentence of section 91 of this title, was restored to that section and has been transferred to section 623 of this title.

§ 93. Repealed. May 29, 1928, ch. 901, § 1(92), 45 Stat. 993

Section, act Mar. 4, 1907, ch. 2907, 34 Stat. 1265, related to statement in annual estimates as to persons employed, their compensation and expenses.

§§ 94 to 95. Transferred

CODIFICATION

Section 94, act June 30, 1914, ch. 131, 38 Stat. 420, which related to inspection of reindeer, was transferred to section 692 of this title.

Section 94a, act May 23, 1908, ch. 192, 35 Stat. 254, which related to inspection of dairy products for export, was transferred to section 693 of this title.

Section 95, acts June 30, 1906, ch. 3913, 34 Stat. 679; June 26, 1934, ch. 756, § 2, 48 Stat. 1225, which related to authorization of appropriations for expenses of inspection, was transferred to section 694 of this title.

§ 96. Repealed. Pub. L. 90-201, § 18, Dec. 15, 1967, 81 Stat. 600

Section, act July 24, 1919, ch. 26, 41 Stat. 241, provided for marking horse meat transported in interstate commerce and is now covered in section 619 of this title.

EFFECTIVE DATE OF REPEAL

Repeal of section effective Dec. 15, 1967, see section 20 of Pub. L. 90-201, set out as a note under section 601 of this title.

§§ 97 to 97d. Omitted

CODIFICATION

Sections 97 to 97d, act July 30, 1947, ch. 356, title I, § 1, 61 Stat. 531, 532, set up a meat inspection fund and provided for payment for meat inspection service by the persons or organizations who were furnished such inspection on and after July 1, 1947. These provisions ceased to be effective on July 1, 1948, under section 98 of this title which requires the cost of such inspection

to be borne by the United States. The unobligated balance in the meat inspection fund was carried to the general fund of the Treasury by act June 19, 1948, ch. 543, § 1, 62 Stat. 515.

§ 98. Transferred

CODIFICATION

Section, act June 5, 1948, ch. 423, 62 Stat. 344, which related to payment of cost of meat inspection, was transferred to section 695 of this title.

§ 99. Repealed. July 28, 1953, ch. 251, title I, § 101, 67 Stat. 208

Section, act Aug. 31, 1951, ch. 374, title I, § 101, 65 Stat. 229, related to reimbursement for excess expenses of meat inspection.

SUBCHAPTER II—IMPORTATION OF CATTLE AND QUARANTINE

§ 101. Suspension of importation of all animals

Whenever, in the opinion of the President, it shall be necessary for the protection of animals in the United States against infectious or contagious diseases, he may, by proclamation, suspend the importation of all or any class of animals for a limited time, and may change, modify, revoke, or renew such proclamation, as the public good may require; and during the time of such suspension the importation of any such animals shall be unlawful.

(Aug. 30, 1890, ch. 839, § 9, 26 Stat. 416.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§ 102. Quarantine of imported animals

The Secretary of Agriculture is authorized, at the expense of the owner, to place and retain in quarantine all neat cattle, sheep, and other ruminants, and all swine, imported into the United States, at such ports as he may designate for such purpose, and under such conditions as he may by regulation prescribe, respectively, for the several classes of animals above described. For this purpose he may have and maintain possession of all lands, buildings, animals, tools, fixtures, and appurtenances in use on August 3, 1890, for the quarantine of neat cattle, and purchase, construct, or rent as may be necessary, and he may appoint veterinary surgeons, inspectors, officers, and employees by him deemed necessary to maintain such quarantine, and provide for the execution of the other provisions of this subchapter.

(Aug. 30, 1890, ch. 839, § 7, 26 Stat. 416.)

REFERENCES IN TEXT

This subchapter, referred to in text, was in the original this Act, meaning act Aug. 30, 1890, ch. 839, 26 Stat. 415, which is classified to sections 18 and 101 to 105 of this title and section 181 of Title 19, Customs Duties. For complete classification of the Act to the Code, see Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§ 103. Importation, except at quarantine ports, prohibited; slaughter of infected animals; appraisal; payment

The importation of all animals described in this subchapter into any port in the United States, except such as may be designated by the Secretary of Agriculture, with the approval of the Secretary of the Treasury, as quarantine stations, is prohibited. The Secretary of Agriculture may cause to be slaughtered such of the animals named in this subchapter as may be, under regulations prescribed by him, adjudged to be infected with any contagious disease, or to have been exposed to infection so as to be dangerous to other animals. The value of animals so slaughtered as being so exposed to infection but not infected may be ascertained by agreement of the Secretary of Agriculture and the owners thereof if practicable; otherwise, by the appraisal by two persons familiar with the character and value of such property, to be appointed by the Secretary of Agriculture, whose decision, if they agree, shall be final; otherwise, the Secretary of Agriculture shall decide between them, and his decision shall be final. The amount of the value thus ascertained shall be paid to the owner thereof out of money in the Treasury appropriated for the use of the Bureau of Animal Industry; but no payment shall be made for any animal imported in violation of the provisions of this subchapter. If any animal subject to quarantine according to the provisions of this subchapter are brought into any port of the United States where no quarantine station is established, the collector of such port shall require the same to be conveyed, by the vessel on which they are imported or are found to the nearest quarantine station, at the expense of the owner.

(Aug. 30, 1890, ch. 839, § 8, 26 Stat. 416.)

REFERENCES IN TEXT

This subchapter, referred to in text, was in the original, this Act, meaning act Aug. 30, 1890, ch. 839, 26 Stat. 415, which is classified to sections 18, and 101 to 105 of this title and section 181 of Title 19, Customs Duties. For complete classification of the Act to the Code, see Tables volume.

TRANSFER OF FUNCTIONS

Functions of the Bureau of Animal Industry were transferred to the Secretary of Agriculture by Reorg. Plan No. 1 of 1947, § 301, eff. July 1, 1947, 12 F.R. 4534, 61 Stat. 952, set out in the Appendix to Title 5, Government Organization and Employees.

For abolition of the offices of collector of customs, see Transfer of Functions note set out under section 44 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§ 104. Importation of diseased animals prohibited; exception

The importation of cattle, sheep, and other ruminants, and swine, which are diseased or infected with any disease, or which shall have been exposed to such infection within sixty days next before their exportation, is prohibited: *Provided*, That the Secretary of Agriculture, within his discretion and under such regulations as he may prescribe, is authorized to permit the admission from Mexico into the

State of Texas of cattle which have been infested with or exposed to ticks upon being freed therefrom, and the admission from the British Virgin Islands into the Virgin Islands of the United States, for slaughter only, of cattle which have been infested with or exposed to ticks upon being freed therefrom. Any person who shall knowingly violate the foregoing provisions shall be deemed guilty of a misdemeanor and shall, on conviction, be punished by a fine not exceeding $5,000, or by imprisonment not exceeding three years, and any vessel or vehicle used in such unlawful importation within the knowledge of the master or owner of such vessel or vehicle that such importation is diseased or has been exposed to infection as herein described, shall be forfeited to the United States.

(Aug. 30, 1890, ch. 839, § 6, 26 Stat. 416; June 28, 1926, ch. 700, § 2, 44 Stat. 775; Feb. 28, 1931, ch. 348, 46 Stat. 1460; July 22, 1954, ch. 558, § 32, 68 Stat. 510; Jan. 28, 1956, ch. 12, § 1, 70 Stat. 5.)

AMENDMENTS

1956—Act Jan. 28, 1956, deleted "and the admission into the Virgin Islands" in the proviso and limited importation of cattle into Virgin Islands of the United States to cattle from the British Virgin Islands intended for slaughter.

1954—Act July 22, 1954, inserted "and the admission into the Virgin Islands" in the proviso.

1931—Act Feb. 28, 1931 struck out "meat" and substituted "before their exportation" for "before their importation" in provisions relating to the prohibition of importation of diseased or infected animals.

EFFECTIVE DATE OF 1954 AMENDMENT

Effective date of act July 22, 1954, amending this section, see section 34 of act July 22, 1954, set out as an Effective Date note under section 1541 of Title 48, Territories and Insular Possessions.

CROSS REFERENCES

Cattle, sheep, swine and meats; importation prohibited in certain cases, see section 1306 of Title 19, Customs Duties.

Offense punishable by imprisonment for term in excess of one year deemed a felony, see section 1 of Title 18, Crimes and Criminal Procedure.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§ 105. Inspection of animals imported or intended for export

The Secretary of Agriculture shall cause careful inspection to be made by a suitable officer of all imported animals described in this subchapter, to ascertain whether such animals are infected with contagious diseases or have been exposed to infection so as to be dangerous to other animals, which shall then either be placed in quarantine or dealt with according to the regulations of the Secretary of Agriculture. All food, litter, manure, clothing, utensils, and other appliances that have been so related to such animals on board ship as to be judged liable to convey infection shall be dealt with according to the regulations of the Secretary of Agriculture. The Secretary of Agriculture may cause inspection to be made of all animals described in this subchapter intended for exportation, and provide for the disinfection of all vessels engaged in the transportation thereof, and of all barges or other vessels used in the conveyance of such animals intended for export to the ocean steamer or other vessels, and of all attendants and their clothing, and of all headropes and other appliances used in such exportation, by such orders and regulations as he may prescribe; and if, upon such inspection, any such animals shall be adjudged, under the regulations of the Secretary of Agriculture, to be infected or to have been exposed to infection so as to be dangerous to other animals, they shall not be allowed to be placed upon any vessel for exportation; the expense of all the inspection and disinfection provided for in this section to be borne by the owners of the vessels on which such animals are exported.

(Aug. 30, 1890, ch. 839, § 10, 26 Stat. 417.)

REFERENCES IN TEXT

This subchapter, referred to in text, was in the original, this Act, meaning act Aug. 30, 1890, ch. 839, 26 Stat. 415, which is classified to sections 18, and 101 to 105 of this title and section 181 of Title 19, Customs Duties. For complete classification of this Act to the Code, see Tables volume.

CROSS REFERENCES

Inspection of animals for export, see section 612 et seq. of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§§ 106, 107. Omitted

CODIFICATION

Sections, acts Aug. 10, 1917, ch. 52, § 9, 40 Stat. 275; Nov. 21, 1918, ch. 212, § 3, 40 Stat. 1048, related to slaughter of tick-infested cattle. Section 12 of act Aug. 10, 1917, provided that the act should cease to be in effect when the national emergency resulting from World War I had passed.

SUBCHAPTER III—PREVENTION OF INTRODUCTION AND SPREAD OF CONTAGION

§ 111. Regulations to prevent contagious diseases

The Secretary of Agriculture shall have authority to make such regulations and take such measures as he may deem proper to prevent the introduction or dissemination of the contagion of any contagious, infectious, or communicable disease of animals and/or live poultry from a foreign country into the United States or from one State or Territory of the United States or the District of Columbia to another, and to seize, quarantine, and dispose of any hay, straw, forage, or similar material, or any meats, hides, or other animal products coming from an infected foreign country to the United States, or from one State or Territory or the District of Columbia in transit to another State or Territory or the District of Columbia whenever in his judgment such action is advisable in order to guard against the introduction or spread of such contagion.

(Feb. 2, 1903, ch. 349, § 2, 32 Stat. 792; Feb. 7, 1928, ch. 30, 45 Stat. 59; July 22, 1954, ch. 558, § 33, 68 Stat. 510; Jan. 28, 1956, ch. 12, § 2, 70 Stat. 5.)

AMENDMENTS

1956—Act Jan. 28, 1956, eliminated proviso "that no such regulations or measures shall pertain to the introduction of live poultry into the Virgin Islands of the United States".

1954—Act July 22, 1954, added the proviso containing an exception with respect to admission of live poultry into the Virgin Islands.

1928—Act Feb. 2, 1928, inserted "and/or live poultry".

EFFECTIVE DATE OF 1954 AMENDMENT

Effective date of act July 22, 1954, amending this section, see section 34 of act July 22, 1954, set out as an Effective Date note under section 1541 of Title 48, Territories and Insular Possessions.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 114g, 122 of this title; title 16 section 1540.

§ 112. Investigations as to pleuropneumonia, and other diseases; regulations

In order to promote the exportation of livestock and/or live poultry from the United States the Secretary of Agriculture shall make special investigation as to the existence of pleuropneumonia, or any contagious, infectious, or communicable disease, along the dividing lines between the United States and foreign countries, and along the lines of transportation from all parts of the United States to ports from which livestock and/or live poultry are exported, and shall, from time to time, establish such regulations concerning the exportation and transportation of livestock and/or live poultry as the results of said investigations may require.

(May 29, 1884, ch. 60, § 4, 23 Stat. 32; Feb. 2, 1903, ch. 349, § 1, 32 Stat. 791; Feb. 7, 1928, ch. 30, 45 Stat. 59.)

CODIFICATION

Originally this section and sections 113, 114, 117, 119, 120, and 130 of this title read "Commissioner" instead of "Secretary" of Agriculture, and this section contained between the words "and" and "shall," in line 10, the additional words "make report of the results of such investigation to the Secretary of the Treasury, who".

The designation of the office of Commissioner of Agriculture was changed by the change of the department into an executive department under a Secretary of Agriculture, by act Feb. 9, 1889, ch. 122, § 1, 25 Stat. 659, set out as section 2202 of Title 7, Agriculture. The authority granted to the Commissioner by the act May 29, 1884, was vested in the Secretary of Agriculture by a provision of act July 14, 1890, ch. 707, 26 Stat. 288, set out as section 2205 of Title 7.

The powers conferred on the Secretary of the Treasury by act May 29, 1884, were conferred on the Secretary of Agriculture by part of section 1 of act Feb. 2, 1903. Remainder of such section 1 is classified to sections 113, 120, and 121 of this title.

AMENDMENTS

1928—Act Feb. 7, 1928, inserted "and/or live poultry".

SHORT TITLE

Act Feb. 2, 1903, classified to sections 112 and 120 to 122 of this title, entitled, "An act to enable the Secretary of Agriculture to more effectually suppress and prevent the spread of contagious and infectious diseases of live stock, and for other purposes" is popularly known as the Cattle Contagious Diseases Act of 1903.

Act May 29, 1884, entitled, "An act for the establishment of a Bureau of Animal Industry, to prevent the exportation of diseased cattle, and to provide means for the suppression and extirpation of pleuro-pneumonia and other contagious diseases among domestic animals" is popularly known as the Animal Industry Act. The Act is classified to sections 112, 113 to 114a-1, 115, 116, 117 to 120, and 130 of this title and section 391 of Title 7, Agriculture.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 118, 119 of this title; title 16 section 1540.

§ 112a. Omitted

CODIFICATION

Section, act Feb. 7, 1928, ch. 30, 45 Stat. 59, which amended acts May 29, 1884, ch. 60, 22 Stat. 31; Feb. 2, 1903, ch. 349, 32 Stat. 791; and Mar. 3, 1905, ch. 1496, 33 Stat. 1264, to include live poultry in their provisions, added "and/or live poultry" following "live stock" wherever the term "live stock" appeared, and extended the penalty provisions of said acts to live poultry, has been omitted on execution of the amendments.

§ 113. Measures to prevent exportation of diseased livestock and live poultry

In order to prevent the exportation from any port of the United States to any port in a foreign country of livestock and/or live poultry affected with any contagious, infectious, or communicable disease, and especially pleuropneumonia, the Secretary of Agriculture is authorized to take such steps and adopt such measures, not inconsistent with the provisions of this Act, as he may deem necessary.

(May 29, 1884, ch. 60, § 5, 23 Stat. 32; Feb. 2, 1903, ch. 349, § 1, 32 Stat. 791; Feb. 7, 1928, ch. 30, 45 Stat. 59.)

REFERENCES IN TEXT

This Act, referred to in text, is act May 29, 1884, ch. 60, 23 Stat. 31, which is popularly known as the Animal Industry Act. For complete classification of this Act to the Code, see Short Title note set out under section 112 of this title and Tables volume.

CODIFICATION

Section is comprised of part of section 1 of act Feb. 2, 1903. Remainder of such section 1 is classified to sections 112, 120, and 121 of this title.

Substitution of Secretary of Agriculture for Commissioner of Agriculture, see Codification note set out under section 112 of this title.

AMENDMENTS

1928—Act Feb. 7, 1928, inserted "and/or live poultry".

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§ 113a. Establishment of research laboratories for foot-and-mouth disease and other animal diseases; research contracts; employment of technicians and scientists; appropriations

The Secretary of Agriculture is authorized to establish research laboratories, including the acquisition of necessary land, buildings, or facilities, and also the making of research contracts under the authority contained in section 427i(a) of title 7, for research and study, in the

United States or elsewhere, of foot-and-mouth disease and other animal diseases which in the opinion of the Secretary constitute a threat to the livestock industry of the United States: *Provided*, That no live virus of foot-and-mouth disease may be introduced for any purpose into any part of the mainland of the United States except coastal islands separated therefrom by water navigable for deep-water navigation and which shall not be connected with the mainland by any tunnel, and except that the Secretary of Agriculture may transport said virus in the original package across the mainland under adequate safeguards, and except further, that in the event of outbreak of foot-and-mouth disease in this country, the Secretary of Agriculture may, at his discretion, permit said virus to be brought into the United States under adequate safeguards. To carry out the provisions of this section, the Secretary is authorized to employ technical experts or scientists: *Provided*, That the number so employed shall not exceed five and that the maximum compensation for each shall not exceed the highest rate of grade 18 of the General Schedule. There is authorized to be appropriated such sums as Congress may deem necessary; in addition, the Secretary is authorized to utilize in carrying out this section, funds otherwise available for the control or eradication of such diseases.

(May 29, 1884, ch. 60, § 12, as added Apr. 24, 1948, ch. 229, 62 Stat. 198, and amended July 31, 1956, ch. 804, title I, § 119, 70 Stat. 742; July 31, 1958, Pub. L. 85-573, 72 Stat. 454; Oct. 11, 1962, Pub. L. 87-793, § 1001(e), 76 Stat. 864; Aug. 14, 1964, Pub. L. 88-426, title III, § 305(1), 78 Stat. 422.)

REFERENCES IN TEXT

The General Schedule, referred to in the text, is set out under section 5332 of Title 5, Government Organization and Employees.

CODIFICATION

Provisions that authorized the Secretary to employ technical experts and scientists "without regard to the Classification Act", meaning the Classification Act of 1923, were omitted as obsolete. Sections 1202 and 1204 of the Classification Act of 1949, 63 Stat. 972, 973, repealed the 1923 Act and all laws or parts of laws inconsistent with the 1949 Act. While section 1106(a) of the 1949 Act provided that references in other laws to the 1923 Act should be held and considered to mean the 1949 Act, it did not have the effect of continuing the exception contained in this section because of section 1106(b) which provided that the application of the 1949 Act to any position, officer, or employee shall not be affected by section 1106(a). The Classification Act of 1949 was repealed by Pub. L. 89-554, Sept. 6, 1966, § 8(a), 80 Stat. 632 (of which section 1 revised and enacted Title 5, Government Organization and Employees, into law). Section 5102 of Title 5 now contains the applicability provisions of the 1949 Act, and section 5103 of Title 5 authorizes the Civil Service Commission to determine the applicability to specific positions and employees.

AMENDMENTS

1962—Pub. L. 87-793 substituted "shall not exceed the highest rate of grade 18 of the General Schedule" for "shall not exceed $19,000 per annum".

1958—Pub. L. 85-573 inserted in the proviso clause of the first sentence the exception clause respecting transportation of virus in original package across mainland under adequate safeguards.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by Pub. L. 87-793 effective on the first day of the first pay period which begins on or after Oct. 11, 1962.

REPEALS

Act July 31, 1956, ch. 804, title I, § 119, 70 Stat. 742, which increased the maximum compensation of technical experts or scientists, was repealed by Pub. L. 88-426, title III, § 305(1), Aug. 14, 1964, 78 Stat. 422.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 118, 119 of this title; title 16 section 1540.

§ 114. Regulations for suppression of diseases; cooperation of States and Territories

It shall be the duty of the Secretary of Agriculture to prepare such rules and regulations as he may deem necessary for the speedy and effectual suppression and extirpation of pleuropneumonia and other dangerous, contagious, infectious, and communicable diseases, and to certify such rules and regulations to the executive authority of each State and Territory, and invite said authorities to cooperate in the execution and enforcement of the provisions of this Act. Whenever the plans and methods of the Secretary of Agriculture shall be accepted by any State or Territory in which pleuropneumonia or other contagious, infectious, or communicable disease is declared to exist, or such State or Territory shall have adopted plans and methods for the suppression and extirpation of said diseases, and such plans and methods shall be accepted by the Secretary of Agriculture, and whenever the governor of a State or other properly constituted authorities signify their readiness to cooperate for the extinction of any contagious, infectious, or communicable disease in conformity with the provisions of this Act, the Secretary of Agriculture is authorized to expend so much of the money appropriated for carrying out the provisions of this Act as may be necessary in such investigations, and in such disinfection and quarantine measures as may be necessary to prevent the spread of the disease from one State or Territory into another.

(May 29, 1884, ch. 60, § 3, 23 Stat. 32.)

REFERENCES IN TEXT

This Act, referred to in text, is act May 29, 1884, ch. 60, 23 Stat. 31, which is popularly known as the Animal Industry Act. For complete classification of this Act to the Code, see Short Title note set out under section 112 of this title and Tables volume.

CODIFICATION

Substitution of Secretary of Agriculture for Commissioner of Agriculture, see Codification note set out under section 112 of this title.

EXTENSION OF PROVISIONS TO LIVE POULTRY

Act Feb. 7, 1928, ch. 30, 45 Stat. 59, extended the provisions of this section to live poultry.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 118, 119 of this title; title 16 section 1540.

§ 114a. Control and eradication of diseases; cooperation of States and farmers' associations; purchase and destruction of diseased animals; definition of State

The Secretary of Agriculture, either independently or in cooperation with States or political subdivisions thereof, farmers' associations and similar organizations, and individuals, is authorized to control and eradicate any communicable diseases of livestock or poultry, including, but not limited to, tuberculosis and paratuberculosis of animals, avian tuberculosis, brucellosis of domestic animals, southern cattle ticks, hog cholera and related swine diseases, scabies in sheep and cattle, dourine in horses, scrapie and blue tongue in sheep, incipient or potentially serious minor outbreaks of diseases of animals, and contagious or infectious diseases of animals (such as foot-and-mouth disease, rinderpest, and contagious pleuropneumonia) which in the opinion of the Secretary constitute an emergency and threaten the livestock industry of the country, including the payment of claims growing out of destruction of animals (including poultry), and of materials, affected by or exposed to any such disease, in accordance with such regulations as the Secretary may prescribe. As used in this section, the term "State" includes the District of Columbia, Puerto Rico, and the Territories and possessions of the United States.

(May 29, 1884, ch. 60, § 11, as added Sept. 21, 1944, ch. 412, title I, § 101(a), 58 Stat. 734, and amended Oct. 30, 1951, ch. 637, § 1, 65 Stat. 693; Aug. 8, 1953, ch. 381, 67 Stat. 493; Aug. 3, 1956, ch. 950, § 2, 70 Stat. 1032; July 2, 1962, Pub. L. 87-518, § 7, 76 Stat. 131.)

PRIOR PROVISIONS

A prior section 11 of act May 29, 1884, which required annual reports to Congress concerning the suppression of contagious diseases among domestic animals, and which was classified to section 560 of Title 5, was repealed by act May 29, 1928, ch. 901, § 1, 45 Stat. 993.

AMENDMENTS

1962—Pub. L. 87-518 inserted "any communicable diseases of livestock or poultry, including, but not limited to," following "eradicate".

1956—Act Aug. 3, 1956, authorized payment of claims for destruction of material affected or exposed to disease.

1953—Act Aug. 8, 1953, provided for the control and eradication of scrapie and blue tongue in sheep, as well as incipient and potentially serious minor outbreaks of diseases of animals.

1951—Act Oct. 30, 1951, substituted "brucellosis of domestic animals" for "Bang's disease of cattle".

APPROPRIATIONS

Section 101(g) of act Sept. 21, 1944, provided that Congress may appropriate such funds as are necessary to accomplish the purpose of this section.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 114c, 114g, 118, 119 of this title; title 16 section 1540.

§ 114a-1. Interstate movement of domestic animals reacting to tests for brucellosis; immediate slaughter; rules and regulations

Domestic animals which have reacted to a test recognized by the Secretary of Agriculture for paratuberculosis or which, never having been vaccinated for brucellosis, have reacted to a test recognized by the Secretary of Agriculture for brucellosis, may be shipped, transported, or otherwise moved from one State, Territory, or the District of Columbia to any other State, Territory, or the District of Columbia for immediate slaughter in accordance with such rules and regulations as the Secretary of Agriculture may prescribe to prevent the dissemination of said diseases from one State, Territory, or the District of Columbia to any other State, Territory, or the District of Columbia. The Secretary of Agriculture may, in his discretion and under such rules and regulations as he may prescribe, permit domestic animals which have been moved from one State, Territory, or the District of Columbia to any other State, Territory, or the District of Columbia, for breeding purposes, and which, subsequent to such movement, have reacted to a test for brucellosis or paratuberculosis recognized by the Secretary of Agriculture, to be reshipped in interstate commerce to the original owner at the point of origin.

(May 29, 1884, ch. 80, § 13, as added Oct. 30, 1951, ch. 637, § 2, 65 Stat. 693.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 118, 119 of this title; title 16 section 1540.

§ 114b. Cooperation with Western Hemisphere countries in animal disease control

The Secretary of Agriculture is authorized to cooperate with the Governments of Mexico, Guatemala, El Salvador, Costa Rica, Honduras, Nicaragua, Belize, Panama, Colombia, and Canada, the Bahama Islands, the Greater Antilles, and the Lesser Antilles, and with international organizations or associations in carrying out operations or measures to eradicate, suppress, or control, or to prevent or retard, any communicable disease of animals or vectors thereof, including but not limited to foot-and-mouth disease, rinderpest, or screw-worm in such countries where he deems such action necessary to protect the livestock, poultry, and related industries of the United States. In performing the operations or measures authorized in sections 114b to 114d-1 of this title, the Governments of such countries shall be responsible for the authority necessary to carry out such operations or measures on all lands and properties therein and for such other facilities and means as in the discretion of the Secretary of Agriculture are necessary. The measure and character of cooperation carried out under said sections on the part of the United States and on the part of the Governments of such countries, including the expenditure or use of funds appropriated pursuant to said sections, shall be such as may be prescribed by the Secretary of Agriculture. Arrangements for the cooperation authorized by said sections shall be made through and in consultation with the Secretary of State. The authority contained in said sections is in addition to and not in substitution for the authority of existing law.

(Feb. 28, 1947, ch. 8, § 1, 61 Stat. 7; July 27, 1966, Pub. L. 89-521, § 1, 80 Stat. 330; Nov. 5,

1971, Pub. L. 92-152, § 1, 85 Stat. 418; Mar. 15, 1976, Pub. L. 94-231, § 3, 90 Stat. 216.)

REFERENCES IN TEXT

Section 114d, included within the reference to sections 114b to 114d-1, was repealed by Pub. L. 86-533, § 1(20), June 29, 1960, 74 Stat. 249.

AMENDMENTS

1976—Pub. L. 94-231 substituted "Belize" for "British Honduras", added ", the Bahama Islands, the Greater Antilles, and the Lesser Antilles, and with international organizations or associations" after "Canada", and added "or vectors thereof" after "any communicable disease of animals".

1971—Pub. L. 92-152 made the provisions applicable to and authorized cooperation of Secretary of Agriculture with Governments of Guatemala, El Salvador, Costa Rica, Honduras, Nicaragua, British Honduras, Panama, Columbia, and Canada, directed operations and measures to be taken against communicable diseases of animals, and included protection of poultry within its scope.

1966—Pub. L. 89-521 authorized the Secretary of Agriculture to cooperate in screw-worm eradication in Mexico.

APPROPRIATIONS

Act Mar. 27, 1947, ch. 22, 61 Stat. 24, provided for an appropriation of $9,000,000 to carry out the provisions of this section during fiscal year 1947.

Section 4 of act Feb. 28, 1947, provided: "There are authorized to be appropriated such sums as may be necessary to carry out this Act [sections 114b to 114d of this title]."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 114c, 114d-1, 129 of this title; title 16 section 1540.

§ 114c. Use of funds for purchase or hire of vehicles and airplanes, printing, and employment of personnel

For purposes of sections 114a, and 114b to 114d-1 of this title, insofar as sections 114b to 114d-1 of this title relate to diseases which in the opinion of the Secretary constitute an emergency and threaten the livestock industry of the country, funds appropriated pursuant thereto may also be used for the purchase or hire of passenger motor vehicles and aircraft, for printing and binding without regard to section 501 of title 44, for personal services in the District of Columbia and elsewhere without regard to the limitations contained in section 947(g) of title 5, including the employment of civilian nationals of Mexico, Guatemala, El Salvador, Costa Rica, Honduras, Nicaragua, British Honduras, Panama, Columbia, and Canada, and for the construction and operation of research laboratories, quarantine stations and other buildings and facilities.

(Feb. 28, 1947, ch. 8, § 2, 61 Stat. 7; Aug. 3, 1956, ch. 950, § 3, 70 Stat. 1033; Nov. 5, 1971, Pub. L. 92-152, § 2, 85 Stat. 419.)

REFERENCES IN TEXT

Section 114d, included in the reference to sections 114b to 114d-1 of this title, was repealed by Pub. L. 86-533, § 1(20), June 29, 1960, 74 Stat. 249.

Section 947(g) of title 5, referred to in the text, was repealed by act Sept. 12, 1950, ch. 946, title III, § 301 (85), 64 Stat. 843.

CODIFICATION

"Section 501 of title 44" was substituted for "section 87 of the Act of January 12, 1895, or section 11 of the Act of March 1, 1919 (U.S.C., title 44, sec. 111)" on authority of section 2(b) of Pub. L. 90-620, Oct. 22, 1968, 82 Stat. 1305, section 1 of which enacted Title 44, Public Printing and Documents.

AMENDMENTS

1971—Pub. L. 92-152 provided for use of funds for employment of civilian nationals of Guatemala, El Salvador, Costa Rica, Honduras, Nicaragua, British Honduras, Panama, Columbia, and Canada.

1956—Act Aug. 3, 1956, inserted in the first sentence "and section 114a of this title, insofar as sections 114b-114d of this title relate to diseases which in the opinion of the Secretary constitute an emergency and threaten the livestock industry of the country".

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 114b, 114d-1, 129 of this title; title 16 section 1540.

§ 114d. Repealed. Pub. L. 86-533, § 1(20), June 29, 1960, 74 Stat. 249

Section, act Feb. 28, 1947, ch. 8, § 3, 61 Stat. 8, related to reports by the Secretary of Agriculture to the Congress with respect to activities carried on under sections 114b and 114c of this title.

§ 114d-1. Cooperation with public and private organizations and individuals in control and eradication of foot-and-mouth disease, rinderpest, and screw-worm

In carrying out sections 114b to 114d-1 of this title the Secretary of Agriculture is further authorized to cooperate with other public and private organizations and individuals.

(Feb. 28, 1947, ch. 8, § 5, as added July 27, 1966, Pub. L. 89-521, § 2, 80 Stat. 330.)

REFERENCES IN TEXT

Section 114d, included within the reference to sections 114b to 114d-1 of this title, was repealed by Pub. L. 86-533, § 120), June 29, 1960, 74 Stat. 249.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 114b, 114c of this title; title 16 section 1540.

§§ 114d-2 to 114d-6. Repealed. Pub. L. 92-152, § 3, Nov. 5, 1971, 85 Stat. 419

Section 114d-2, Pub. L. 90-388, § 1, July 6, 1968, 82 Stat. 294, provided for cooperation with Central America in control and eradication of foot-and-mouth disease or rinderpest, and is now covered by section 114b of this title.

Section 114d-3, Pub. L. 90-388, § 2, July 6, 1968, 82 Stat. 294, provided for uses of funds, and is now covered by section 114c of this title.

Section 114d-4, Pub. L. 90-388, § 3, July 6, 1968, 82 Stat. 294, defined governments of Central America, and is now covered by sections 114b and 114c of this title.

Section 114d-5, Pub. L. 90-388, § 4, July 6, 1968, 82 Stat. 294, provided for cooperation with public and private organizations and individuals, and is now covered by section 114d-1 of this title.

Section 114d-6, Pub. L. 90-388, § 5, July 6, 1968, 82 Stat. 294, provided for authorization of appropriations, and is now covered in Appropriations note set out under section 114b of this title.

§ 114e. Control and eradication of cattle grubs; research and investigations

In order to protect, promote, and conserve livestock and livestock products and to minimize losses, the Secretary of Agriculture, either independently or in cooperation with States or subdivisions thereof, farmers' associations, and other organizations and individuals, it[1] is authorized to increase and intensify research and investigations into problems and methods relating to the eradication of cattle grubs and to undertake measures to eradicate these parasites.

(June 16, 1948, ch. 477, § 1, 62 Stat. 458.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 114f of this title; title 16 section 1540.

§ 114f. Definitions; authorization of appropriations

As used in section 114e of this title, the term "State" includes the District of Columbia and the Territories and possessions of the United States. There is authorized to be appropriated such sums as may be necessary to carry out section 114e of this title. Funds appropriated pursuant to this section shall be expended in accordance with procedures prescribed by the Secretary.

(June 16, 1948, ch. 477, § 2, 62 Stat. 458.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§ 114g. Hog cholera eradication program

In order to safeguard the health of the swine herds of the Nation, to prevent the spread of hog cholera, to decrease substantially the estimated $50,000,000 annual loss from hog cholera, to expand export markets for pork and pork products now restricted on account of hog cholera, and to otherwise protect the public interest, the Secretary of Agriculture is directed (1) to initiate a national hog cholera eradication program in cooperation with the several States under the provisions of section 114a of this title and related legislation, and (2) to prohibit or restrict, pursuant to the authority vested in him under the provisions of section 111 of this title the interstate movement of virulent hog cholera virus or other hog cholera virus to the extent he determines necessary in order to effectuate such eradication program.

(Pub. L. 87-209, § 1, Sept. 6, 1961, 75 Stat. 481.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 114h of this title; title 16 section 1540.

§ 114h. Advisory committee

(a) Establishment; membership

The Secretary of Agriculture is authorized and directed to establish an advisory committee composed of (1) eleven members selected from representatives of the swine and related industries, State and local government agencies, professional and scientific groups, and the general public, and (2) one member selected from the officers and employees of the Department of Agriculture who shall serve as chairman of the Committee. The Committee shall meet at the call of the Secretary.

(b) Functions

It shall be the function of the Committee to advise the Secretary with respect to the initiation of the national hog cholera eradication program referred to in section 114g of this title, and with respect to the development of plans and procedures for carrying out such program.

(c) Employment status; expenses

Committee members other than the chairman shall not be deemed to be employees of the United States and shall not be entitled to compensation, but the Secretary is authorized to pay their travel and subsistence expenses (or per diem in lieu thereof) in connection with their attendance at meetings of the Committee.

(Pub. L. 87-209, § 2, Sept. 6, 1961, 75 Stat. 481.)

TERMINATION OF ADVISORY COMMITTEES

Advisory Committees in existence on Jan. 5, 1973, to terminate not later than the expiration of the two-year period following Jan. 5, 1973, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such two-year period, or in the case of a committee established by the Congress, its duration is otherwise provided by law, see section 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§ 115. Transportation of diseased livestock and live poultry prohibited

No railroad company within the United States, or the owners or masters of any steam or sailing or other vessel or boat, shall receive for transportation or transport from one State or Territory to another, or from any State into the District of Columbia, or from the District into any State, any livestock and/or live poultry affected with any contagious, infectious, or communicable disease, and especially the disease known as pleuropneumonia; nor shall any person, company, or corporation deliver for such transportation to any railroad company, or master or owner of any boat or vessel, any livestock and/or live poultry, knowing them to be affected with any contagious, infectious, or communicable disease; nor shall any person, company, or corporation drive on foot, or transport in private conveyance from one State or Territory to another, or from any State into the District of Columbia, or from the District into any State, any livestock and/or live poultry, knowing them to be affected with any contagious, infectious, or communicable disease, and especially the disease known as pleuropneumonia: *Provided*, That such livestock or poultry may be so delivered and received for such transportation and so transported and moved if the Secretary of Agriculture determines that such action will not endanger the livestock or poultry of the United States and authorizes such action, and such delivery, receipt, transportation, and movement are made in strict compliance with such rules and regulations as the Secretary of Agriculture may pre-

[1] So in original.

scribe to protect the livestock and poultry of the United States.

(May 29, 1884, ch. 60, § 6, 23 Stat. 32; June 28, 1926, ch. 700, § 1, 44 Stat. 774; Feb. 7, 1928, ch. 30, 45 Stat. 59; Oct. 9, 1962, Pub. L. 87-763, 76 Stat. 762.)

CODIFICATION

Act May 29, 1884, as amended by act June 28, 1926, also contained the following proviso: "That until May 1, 1928, cattle infested with or exposed to cattle fever ticks may be shipped in interstate commerce for immediate slaughter after one dipping in accordance with such regulations as the Secretary of Agriculture may prescribe."

AMENDMENTS

1962—Pub. L. 87-763 inserted proviso permitting such livestock or poultry to be delivered and received for transportation and so transported and moved if the Secretary determines that such action will not endanger the livestock or poultry of the United States and authorizes such action, and such delivery, receipt, transportation, and movement are made in strict compliance with such rules and regulations as the Secretary may prescribe.

1928—Act Feb. 7, 1928, inserted "and/or live poultry" following "livestock", wherever appearing.

1926—Act June 28, 1926, eliminated provision deeming splenetic or Texas fever not a communicable disease as to cattle unloaded only to be fed and watered on the way by rail to market for slaughter.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 117, 118, 119 of this title; title 16 section 1540.

§ 116. Shipment of certain cattle excepted

Cattle which have reacted to the tuberculin test may be shipped, transported, or moved from one State, Territory, or the District of Columbia to any other State, Territory, or the District of Columbia, for immediate slaughter, in accordance with such rules and regulations as shall be prescribed by the Secretary of Agriculture. The said Secretary of Agriculture may, in his discretion, and under such rules and regulations as he may prescribe, permit cattle which have been shipped for breeding or feeding purposes from one State, Territory, or the District of Columbia to another State, Territory, or the District of Columbia, and which have reacted to the tuberculin test subsequent to such shipment, to be reshipped in interstate commerce to the original owner.

(May 29, 1884, ch. 60, 23 Stat. 31; May 31, 1920, ch. 217, 41 Stat. 699.)

AMENDMENTS

1920—Act May 31, 1920, amended act May 29, 1884, without amending any particular section thereof, by enacting provisions set out as this section. For classification of act May 29, 1884, to the Code, see Short Title note set out under section 112 of this title and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§ 117. Notice of existence of contagion to railroads; transportation of diseased stock or live poultry; penalty

It shall be the duty of the Secretary of Agriculture to notify, in writing, the proper officials or agents of any railroad, steamboat, or other transportation company doing business in or through any infected locality, and by publication in such newspapers as he may select, of the existence of said contagion; and any person or persons operating any such railroad, or master or owner of any boat or vessel, or owner or custodian of or person having control over such cattle or other livestock and/or live poultry within such infected district, who shall knowingly violate the provisions of section 115 of this title shall be guilty of a misdemeanor and, upon conviction, shall be punished by a fine of not less than $100 nor more than $5,000 or by imprisonment for not more than one year, or by both such fine and imprisonment.

(May 29, 1884, ch. 60, § 7, 23 Stat. 32; Feb. 7, 1928, ch. 30, 45 Stat. 59.)

CODIFICATION

Substitution of Secretary of Agriculture for Commissioner of Agriculture, see Codification note set out under section 112 of this title.

AMENDMENTS

1928—Act Feb. 7, 1928 inserted "and/or live poultry" following "livestock".

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 118, 119 of this title; title 16 section 1540.

§ 118. Duty of United States attorneys

It shall be the duty of the several United States attorneys to prosecute all violations of this Act which shall be brought to their notice or knowledge by any person making the complaint under oath; and the same shall be heard before any district court of the United States or Territorial court holden within the district in which such violation of this Act has been committed.

(May 29, 1884, ch. 60, § 9, 23 Stat. 33; June 25, 1948, ch. 646, § 1, 62 Stat. 869.)

REFERENCES IN TEXT

This Act, referred to in text, is act May 29, 1884, ch. 60, 23 Stat. 31, which is popularly known as the Animal Industry Act. For complete classification of this Act to the Code, see Short Title note set out under section 112 of this title and Tables volume.

CHANGE OF NAME

Act June 25, 1948, eff. Sept. 1, 1948, substituted "United States attorneys" for "United States district attorneys". See section 541 of Title 28, Judiciary and Judicial Procedure.

REPEALS

Act June 25, 1948, ch. 646, § 39, 62 Stat. 992, repealed act Mar. 3, 1911, ch. 231, § 289, 36 Stat. 1167, formerly cited in text.

EXTENSION OF PROVISIONS TO LIVE POULTRY

Act Feb. 7, 1928, ch. 30, 45 Stat. 59, extended the provisions of this section to live poultry.

FEDERAL RULES OF CRIMINAL PROCEDURE

Continuance of section under rule 18, see note by Advisory Committee under rule 18, Title 18, Appendix, Crimes and Criminal Procedure.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§ 119. Agents to examine and report on methods of treatment of animals, and means for suppression of diseases

The Secretary of Agriculture is authorized to appoint two competent agents, who shall be practical stock raisers or experienced business men familiar with questions pertaining to commercial transactions in livestock and/or live poultry, whose duty it shall be, under the instructions of the said Secretary of Agriculture, to examine and report upon the best methods of treating, transporting, and caring for animals, and the means to be adopted for the suppression and extirpation of contagious pleuropneumonia, and to provide against the spread of other dangerous contagious, infectious, and communicable diseases. The compensation of said agents shall be at the rate of $10 per diem, with all necessary expenses, while engaged in the actual performance of their duties under this Act, when absent from their usual place of business or residence as such agent.

(May 29, 1884, ch. 60, § 2, 23 Stat. 31; Feb. 9, 1889, ch. 122, § 1, 25 Stat. 659; July 14, 1890, ch. 707, 26 Stat. 288; Feb. 7, 1928, ch. 30, 45 Stat. 59.)

References in Text

This Act, referred to in text, is act May 29, 1884, ch. 60, 23 Stat. 31, which is popularly known as the Animal Industry Act. For complete classification of this Act to the Code, see Short Title note set out under section 112 of this title and Tables volume.

Codification

Substitution of Secretary of Agriculture for Commissioner of Agriculture, see Codification note set out under section 112 of this title.

Amendments

1928—Act Feb. 7, 1928 inserted "and/or live poultry" following "livestock".

Section Referred to in Other Sections

This section is referred to in sections 113, 114, 118 of this title; title 16 section 1540.

§ 120. Regulation of exportation and transportation of infected livestock and live poultry

In order to enable the Secretary of Agriculture to effectually suppress and extirpate contagious pleuropneumonia, foot-and-mouth disease, and other dangerous contagious, infectious, and communicable diseases in cattle and other livestock and/or live poultry, and to prevent the spread of such diseases, he is authorized and directed from time to time to establish such rules and regulations concerning the exportation and transportation of livestock and/or live poultry from any place within the United States where he may have reason to believe such diseases may exist into and through any State or Territory, and into and through the District of Columbia and to foreign countries as he may deem necessary, and all such rules and regulations shall have the force of law.

(May 29, 1884, ch. 60, §§ 4, 5, 23 Stat. 32; Feb. 2, 1903, ch. 349, § 1, 32 Stat. 791; Feb. 7, 1928, ch. 30, 45 Stat. 59.)

Codification

Section is comprised of part of section 1 of act Feb. 2, 1903. Remainder of such section 1 is classified to sections 112, 113, and 121 of this title. The words "including the Indian Territory" which followed the word "Territory" in the original text of this section were omitted as obsolete.

Substitution of Secretary of Agriculture for Commissioner of Agriculture, see Codification note set out under section 112 of this title.

Amendments

1928—Act Feb. 7, 1928 inserted "and/or live poultry" following "livestock", wherever appearing.

Section Referred to in Other Sections

This section is referred to in sections 113, 114, 118, 119, 121, 122 of this title; title 16 section 1540.

§ 121. Shipments from areas suspected infected; control of animals and live poultry

Whenever any inspector or assistant inspector of the Bureau of Animal Industry shall issue a certificate showing that such officer had inspected any cattle or other livestock and/or live poultry which were about to be shipped, driven, or transported from such locality to another as stated in section 120 of this title, and had found them free from Texas or splenetic fever infection, pleuropneumonia, foot-and-mouth disease, or any other infectious, contagious, or communicable disease, such animals, so inspected and certified, may be shipped, driven, or transported from such place into and through any State or Territory, and into and through the District of Columbia, or they may be exported from the United States without further inspection or the exaction of fees of any kind, except such as may at any time be ordered or exacted by the Secretary of Agriculture; and all such animals shall at all times be under the control and supervision of the Bureau of Animal Industry of the Agricultural Department for the purposes of such inspection.

(Feb. 2, 1903, ch. 349, § 1, 32 Stat. 791; Feb. 7, 1928, ch. 30, 45 Stat. 59.)

Codification

Section is comprised of part of section 1 of act Feb. 2, 1903. Remainder of such section 1 is classified to sections 112, 113 and 120 of this title.

The words "including the Indian territory" which followed the word "Territory" in the original text of this section was omitted as obsolete.

Amendments

1928—Act Feb. 7, 1928 inserted "and/or live poultry" following "livestock".

Section Referred to in Other Sections

This section is referred to in section 122 of this title; title 16 section 1540.

§ 122. Offenses; penalty

Any person, company, or corporation knowingly violating the provisions of this Act or the orders or regulations made in pursuance thereof shall be guilty of a misdemeanor, and on conviction shall be punished by a fine of not less than $100 nor more than $1,000, or by imprisonment not more than one year, or by both such fine and imprisonment.

(Feb. 2, 1903, ch. 349, § 3, 32 Stat. 792.)

REFERENCES IN TEXT

This Act, referred to in text, is act Feb. 2, 1903, ch. 349, 32 Stat. 791, which enacted sections 111, 121, and 122 of this title and amended sections 112, 113, and 120 of this title. For complete classification of this Act to the Code, see Tables volume.

EXTENSION OF PROVISIONS TO LIVE POULTRY

Act Feb. 7, 1928, ch. 30, 45 Stat. 59, extended the provisions of this section to live poultry.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§ 123. Quarantine

The Secretary of Agriculture is authorized and directed to quarantine any State or Territory or the District of Columbia, or any portion of any State or Territory or the District of Columbia, when he shall determine the fact that any animals and/or live poultry in such State or Territory or District of Columbia are affected with any contagious, infectious, or communicable disease of livestock or poultry or that the contagion of any such disease exists or that vectors which may disseminate any such disease exist in such State or Territory or the District of Columbia; and the Secretary of Agriculture is directed to give written or printed notice of the establishment of quarantine to the proper officers of railroad, steamboat, or other transportation companies doing business in or through any quarantined State or Territory or the District of Columbia, and to publish in such newspapers in the quarantined State or Territory or the District of Columbia, as the Secretary of Agriculture may select, notice of the establishment of quarantine.

(Mar. 3, 1905, ch. 1496, § 1, 33 Stat. 1264; Feb. 7, 1928, ch. 30, 45 Stat. 59; July 2, 1962, Pub. L. 87-518, § 8(a), 76 Stat. 131.)

AMENDMENTS

1962—Pub. L. 87-518 authorized quarantine upon the determination that any animals or poultry are affected with a communicable disease of livestock or poultry or that the contagion of any such disease exists or that vectors which may disseminate any such disease exist.

1928—Act Feb. 7, 1928 inserted "and/or live poultry" following "livestock".

SHORT TITLE

This section and sections 124 to 127 of this title are from act Mar. 3, 1905, entitled "An act to enable the Secretary of Agriculture to establish and maintain quarantine districts, to permit and regulate the movement of cattle and other live stock therefrom, and for other purposes and constitute the Cattle Contagious Diseases Act of 1905."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 125, 128 of this title; title 16 section 1540.

§ 124. Transportation or delivery therefor from quarantined State or Territory or portion thereof, of quarantined animals and live poultry, forbidden

No railroad company or the owners or masters of any steam or sailing or other vessel or boat shall receive for transportation or transport from any quarantined State or Territory or the District of Columbia, or from the quarantined portion of any State or Territory or the District of Columbia, into any other State or Territory or the District of Columbia, any quarantined animals, and/or live poultry, except as hereinafter provided; nor shall any person, company, or corporation deliver for such transportation to any railroad company, or to the master or owner of any boat or vessel, any quarantined animals and/or live poultry, except as hereinafter provided; nor shall any person, company, or corporation drive on foot, or cause to be driven on foot, or transport in private conveyance or cause to be transported in private conveyance, from a quarantine State or Territory or the District of Columbia, or from the quarantined portion of any State or Territory or the District of Columbia, into any other State or Territory or the District of Columbia, and quarantined animals and/or live poultry, except as hereinafter provided.

(Mar. 3, 1905, ch. 1496, § 2, 33 Stat. 1264; Feb. 7, 1928, ch. 30, 45 Stat. 59; July 2, 1962, Pub. L. 87-518, § 8(b), 76 Stat. 131.)

AMENDMENTS

1962—Pub. L. 87-518 substituted "quarantined animals" for "cattle or other livestock", wherever appearing.

1928—Act Feb. 7, 1928 inserted "and/or live poultry" following "livestock", wherever appearing.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 127, 128 of this title; title 16 section 1540.

§ 125. Regulations for inspection, disinfection, and certification, and delivery and shipment of quarantined animals and live poultry from State or Territory

It shall be the duty of the Secretary of Agriculture, and he is authorized and directed, when the public safety will permit, to make and promulgate rules and regulations which shall permit and govern the inspection, disinfection, certification, treatment, handling, and method and manner of delivery and shipment of quarantined animals and/or live poultry from a quarantined State or Territory or the District of Columbia, and from the quarantined portion of any State or Territory or the District of Columbia, into any other State or Territory or the District of Columbia; and the Secretary of Agriculture shall give notice of such rules and regulations in the manner provided in section 123 of this title for notice of establishment of quarantine.

(Mar. 3, 1905, ch. 1496, § 3, 33 Stat. 1265; Feb. 7, 1928, ch. 30, 45 Stat. 59; July 2, 1962, Pub. L. 87-518, § 8(b), 76 Stat. 131.)

CODIFICATION

In the original "section 123 of this title" read "section 2 of this Act", meaning section 2 of act Mar. 3, 1905, which is classified to section 124 of this title. For purposes of codification the reference was made to section 123 of this title containing the provision respecting notice.

AMENDMENTS

1962—Pub. L. 87-518 substituted "quarantined animals" for "cattle or other livestock".

1928—Act Feb. 7, 1928 inserted "and/or live poultry" following "livestock".

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 126, 128 of this title; title 16 section 1540.

§ 126. Moving quarantined animals and live poultry from State or Territory, under regulations

Quarantined animals and/or live poultry may be moved from a quarantined State or Territory or the District of Columbia, or from the quarantined portion of any State or Territory or the District of Columbia, into any other State or Territory or the District of Columbia, under and in compliance with the rules and regulations of the Secretary of Agriculture, made and promulgated in pursuance of the provisions of section 125 of this title; but it shall be unlawful to move, or to allow to be moved, any quarantined animals and/or live poultry from any quarantined State or Territory or the District of Columbia, or from the quarantined portion of any State or Territory or the District of Columbia, into any other State or Territory or the District of Columbia, in manner or method or under conditions other than those prescribed by the Secretary of Agriculture.

(Mar. 3, 1905, ch. 1496, § 4, 33 Stat. 1265; Feb. 7, 1928, ch. 30, 45 Stat. 59; July 2, 1962, Pub. L. 87-518, § 8(b), 76 Stat. 131.)

AMENDMENTS

1962—Pub. L. 87-518 substituted "quarantined animals" for "cattle or other livestock", wherever appearing.

1928—Act Feb. 7, 1928 inserted "and/or live poultry" following "livestock", wherever appearing.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 127, 128 of this title; title 16 section 1540.

§ 127. Transportation from quarantined State, Territory, etc.; penalty

Any person, company, or corporation violating the provisions of sections 124 or 126 of this title shall be guilty of a misdemeanor, and on conviction shall be punished by a fine of not less than $100 nor more than $1,000, or by imprisonment not more than one year, or by both such fine and imprisonment.

(Mar. 3, 1905, ch. 1496, § 6, 33 Stat. 1265.)

EXTENSION OF PROVISIONS TO LIVE POULTRY

Act Feb. 7, 1928, ch. 30, 45 Stat. 59, extended the provisions of this section to live poultry.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 128 of this title; title 16 section 1540.

§ 128. Extension of quarantine law to carriers in interstate commerce

The provisions of sections 123 to 127 of this title shall apply to any railroad company or other common carrier whose road or line forms any part of a route over which quarantined animals are transported in the course of shipment from any quarantined State or Territory or the District of Columbia, or from the quarantined portion of any State or Territory or the District of Columbia into any other State or Territory or the District of Columbia.

(June 30, 1914, ch. 131, 38 Stat. 419; July 2, 1962, Pub. L. 87-518, § 9, 76 Stat. 131.)

CODIFICATION

Section is from the Department of Agriculture Appropriation Act, 1915.

AMENDMENTS

1962—Pub. L. 87-518 substituted "quarantined animals" for "cattle or other livestock".

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§ 129. Expenses for arrest and eradication of contagious or infectious diseases of animals; transfer of appropriations

The Secretary may transfer from other appropriations or funds available to the agencies or corporations of the Department such sums as he may deem necessary, to be available only in emergencies for the arrest and eradication of foot-and-mouth disease, rinderpest, contagious pleuropneumonia, or other contagious or infectious diseases of animals, or European fowl pests and similar diseases in poultry, and for expenses in accordance with sections 114b and 114c of this title, and any unexpended balances of funds transferred for such emergency purposes in the fiscal year 1976 shall be merged with such transferred amounts.

(Pub. L. 94-351, title I, § 101, July 12, 1976, 90 Stat. 854.)

SIMILAR PROVISIONS

Section is from the Agriculture and Related Agencies Appropriations Act, 1977, Pub. L. 94-351, title I, § 101, July 12, 1976, 90 Stat. 854. Similar provisions were contained in the following prior appropriation acts:

Oct. 21, 1975, Pub. L. 94-122, title I, § 101, 89 Stat. 645.

Dec. 31, 1974, Pub. L. 93-563, title I, § 101, 88 Stat. 1824.

Oct. 24, 1973, Pub. L. 93-135, title I, § 101, 87 Stat. 472.

Aug. 22, 1972, Pub. L. 92-399, title I, § 101, 86 Stat. 594.

Aug. 10, 1971, Pub. L. 92-73, title I, § 101, 85 Stat. 185.

Dec. 22, 1970, Pub. L. 91-566, title I, § 101, 84 Stat. 1482.

Nov. 26, 1969, Pub. L. 91-127, title I, § 101, 83 Stat. 246.

Aug. 8, 1968, Pub. L. 90-463, title I, § 101, 82 Stat. 640.

Oct. 24, 1967, Pub. L. 90-113, title I, § 101, 81 Stat. 321.

Sept. 7, 1966, Pub. L. 89-556, title I, § 101, 80 Stat. 690.

Nov. 2, 1965, Pub. L. 89-316, title I, § 101, 79 Stat. 1166.

Sept. 2, 1964, Pub. L. 88-573, title I, § 101, 78 Stat. 868.

Dec. 30, 1963, Pub. L. 88-250, title I, § 101, 77 Stat. 821.

Oct. 24, 1962, Pub. L. 87-879, title I, § 101, 76 Stat. 1204.

July 26, 1961, Pub. L. 87-112, title I, § 101, 75 Stat. 228.

June 29, 1960, Pub. L. 86-532, title I, § 101, 74 Stat. 233.

July 8, 1959, Pub. L. 86-80, title I, § 101, 73 Stat. 168.

June 13, 1958, Pub. L. 85-459, title I, § 101, 72 Stat. 189.

Aug. 2, 1957, Pub. L. 85-118, title I, § 101, 71 Stat. 330.
June 4, 1956, ch. 355, title I, § 101, 70 Stat. 230.
May 23, 1955, ch. 43, title I, § 101, 69 Stat. 52.
June 29, 1954, ch. 409, title I, § 101, 68 Stat. 305.
July 28, 1953, ch. 251, title III, § 301, 67 Stat. 223.
July 5, 1952, ch. 574, title III, § 301, 66 Stat. 354.
Aug. 31, 1951, ch. 374, title II, § 201, 65 Stat. 243.
Sept. 6, 1950, ch. 896, ch. VI, title I, § 101, 64 Stat. 661.
June 29, 1949, ch. 280, title I, § 101, 63 Stat. 332.
June 19, 1948, ch. 543, § 1, 62 Stat. 515.
July 30, 1947, ch. 356, title I, § 1, 61 Stat. 532.
June 22, 1946, ch. 445, § 1, 60 Stat. 278.
May 5, 1945, ch. 109, § 1, 59 Stat. 144.
June 28, 1944, ch. 296, § 1, 58 Stat. 434.
July 12, 1943, ch. 215, § 1, 57 Stat. 403.
July 22, 1942, ch. 516, § 1, 56 Stat. 676.
July 1, 1941, ch. 267, § 1, 55 Stat. 418.
June 25, 1940, ch. 421, § 1, 54 Stat. 542.
June 30, 1939, ch. 253, title I, 53 Stat. 951.
June 16, 1938, ch. 464, title I, 52 Stat. 722.
June 29, 1937, ch. 404, 50 Stat. 406.
June 4, 1936, ch. 489, 49 Stat. 1432.
May 17, 1935, ch. 131, title I, § 1, 49 Stat. 257.
Mar. 26, 1934, ch. 89, 48 Stat. 477.
Mar. 3, 1933, ch. 203, 47 Stat. 1442.
July 7, 1932, ch. 443, 47 Stat. 620.
Feb. 23, 1931, ch. 278, 46 Stat. 1252.
May 27, 1930, ch. 341, 46 Stat. 403.
Feb. 16, 1929, ch. 227, 45 Stat. 1198.
May 16, 1928, ch. 572, 45 Stat. 548.
Jan. 18, 1927, ch. 39, 44 Stat. 1005.
May 11, 1926, ch. 286, 44 Stat. 529.
Feb. 10, 1925, ch. 200, 43 Stat. 851.
Dec. 5, 1924, ch. 4, § 1, 43 Stat. 683.
June 5, 1924, ch. 266, 43 Stat. 458.
Apr. 2, 1924, ch. 81, § 1, 43 Stat. 40.
Feb. 26, 1923, ch. 119, 42 Stat. 1318.
May 11, 1922, ch. 185, 42 Stat. 536.
Mar. 4, 1917, ch. 179, 39 Stat. 1167.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§ 130. Pleuropneumonia in District of Columbia; duties of Council of the District of Columbia

Whenever any contagious, infectious, or communicable disease affecting domestic animals or live poultry, and especially the disease known as pleuropneumonia, shall be brought into or shall break out in the District of Columbia, it shall be the duty of the Council of said District to take measures to suppress the same promptly and to prevent the same from spreading; and for this purpose the said Council is empowered to order and require that any premises, farm, or farms where such disease exists, or has existed, be put in quarantine; to order all or any animals coming into the District to be detained at any place or places for the purpose of inspection and examination; to prescribe regulations for and to require the destruction of animals or live poultry affected with contagious, infectious, or communicable disease, and for the proper disposition of their hides and carcasses; to prescribe regulations for disinfection, and such other regulations as they may deem necessary to prevent infection or contagion being communicated, and shall report to the Secretary of Agriculture whatever it may do in pursuance of the provisions of this section.

(May 29, 1884, ch. 60, § 8, 23 Stat. 33; 1967 Reorg. Plan No. 3, § 402(430), eff. Aug. 11, 1967, 32 F.R. 11669, 81 Stat. 948; Pub. L. 93-198, title IV, § 401, Dec. 24, 1973, 88 Stat. 793.)

CODIFICATION

Substitution of Secretary of Agriculture for Commissioner of Agriculture, see Codification note set out under section 112 of this title.

Section is also set out as section 1-230a of the District of Columbia Code.

TRANSFER OF FUNCTIONS

"Council of the District of Columbia" was substituted for "District of Columbia Council" pursuant to section 401 of Pub. L. 93-198. The District of Columbia Council, as established by Reorg. Plan No. 3 of 1967, was abolished as of noon Jan. 2, 1975, by Pub. L. 93-198, title VII, § 711, Dec. 24, 1973, 87 Stat. 818, classified to section 1-131 of the District of Columbia Code, and replaced by the Council of the District of Columbia, as provided by section 401 of Pub. L. 93-198, classified to section 1-141 of the District of Columbia Code.

Previously, references to the Board of Commissioners of the District of Columbia had been changed to the District of Columbia Council pursuant to section 402(430) of Reorganization Plan No. 3 of 1967, 32 F.R. 11669, effective Nov. 3, 1967, set out in the Appendix to Title 5, Government Organization and Employees, which transferred the regulatory and other functions of the Board of Commissioners relating to the prescribing of regulations for the destruction of animals or live poultry affected by contagious, infectious, or communicable disease, and for the proper disposition of their hides and carcasses, and the prescribing of regulations for disinfection and other regulations under this section to the District of Columbia Council, subject to the right of the Commissioner as provided by section 406 of the Plan. For provisions establishing the District of Columbia Council, see section 201 of the Reorg. Plan No. 3 of 1967.

EXTENSION OF PROVISIONS TO LIVE POULTRY

Act Feb. 7, 1928, ch. 30, 45 Stat. 59, extended the provisions of this section to live poultry.

CROSS REFERENCES

Diseases and quarantine in the District of Columbia, see sections 111 and 123 to 127 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 113, 114, 118, 119 of this title; title 16 section 1540.

§ 131. Fences along international boundary lines to keep out diseased animals

The Secretary of Agriculture may permit the erection of fences along international boundary lines, but entirely within the territory of the United States, for the purpose of keeping out diseased animals.

(May 26, 1910, ch. 256, 36 Stat. 440.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§ 132. Transferred

CODIFICATION

Section, act May 23, 1908, ch. 192, 35 Stat. 254, which related to inspection of dairy products for export, was transferred to section 693 of this title.

§ 133. Repealed. July 13, 1949, ch. 307, 63 Stat. 410

Section, act July 24, 1946, ch. 592, 60 Stat. 633, related to the establishment of a quarantine station on Swan Island.

§ 134. Definitions

As used in this Act unless the context indicates otherwise—

(a) The term "Secretary" means the Secretary of Agriculture.

(b) The term "animals" means all members of the animal kingdom including birds, whether domesticated or wild, but not including man.

(c) The term "United States" means the States, Puerto Rico, Guam, the Virgin Islands of the United States, and the District of Columbia.

(d) The term "interstate" means from a State or other area included in the definition of "United States" to or through any other State or other such area.

(Pub. L. 87-518, § 1, July 2, 1962, 76 Stat. 129.)

REFERENCES IN TEXT

This Act, referred to in text, is Pub. L. 87-518, July 2, 1962, 76 Stat. 129, which enacted sections 134 to 134h of this title and amended sections 114a, 123 to 126, and 128 of this title and section 1114 of Title 18, Crimes and Criminal Procedure. For complete classification of this Act to the Code, see Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134e, 134f, 134g, 134h of this title; title 16 section 1540.

§ 134a. Seizure, quarantine, and disposal of livestock or poultry to guard against introduction or dissemination of communicable disease

(a) Authority of Secretary

The Secretary, whenever he deems it necessary in order to guard against the introduction or dissemination of a communicable disease of livestock or poultry, may seize, quarantine, and dispose of, in a reasonable manner taking into consideration the nature of the disease and the necessity of such action to protect the livestock or poultry of the United States: (1) any animals which he finds are moving or are being handled or have moved or have been handled in interstate or foreign commerce contrary to any law or regulation administered by him for the prevention of the introduction or dissemination of any communicable disease of livestock or poultry; (2) any animals which he finds are moving into the United States, or interstate, and are affected with or have been exposed to any communicable disease dangerous to livestock or poultry; and (3) any animals which he finds have moved into the United States, or interstate, and at the time of such movement were so affected or exposed.

(b) Determination of extraordinary emergency due to dangerous communicable disease; seizure, quarantine, and disposal of animals; action authorized only if adequate measures not taken by State or other jurisdiction; notice to State or other jurisdiction

Whereas the existence of any dangerous, communicable disease of livestock or poultry, such as foot-and-mouth disease, rinderpest, or European fowl pest, on any premises in the United States would constitute a threat to livestock and poultry of the Nation and would seriously burden interstate and foreign commerce, whenever the Secretary determines that an extraordinary emergency exists because of the outbreak of such a disease anywhere in the United States, and that such outbreak threatens the livestock or poultry of the United States, he may seize, quarantine, and dispose of, in such manner as he deems necessary or appropriate, any animals in the United States which he finds are or have been affected with or exposed to any such disease and the carcasses of any such animals and any products and articles which he finds were so related to such animals as to be likely to be a means of disseminating any such disease: *Provided,* That action shall be taken under this subsection only if the Secretary finds that adequate measures are not being taken by the State or other jurisdiction. The Secretary shall notify the appropriate official of the State or other jurisdiction before any action is taken in any such State or other jurisdiction pursuant to this subsection.

(c) Notice to owner to quarantine or to dispose of animal, carcass, product, or article; action on failure to comply; costs

The Secretary in writing may order the owner of any animal, carcass, product, or article referred to in subsection (a) or (b) of this section, or the agent of such owner, to maintain in quarantine, and to dispose of such animal, carcass, product, or article in such manner as the Secretary may direct pursuant to authority vested in him by such subsections. If such owner or agent fails to do so after receipt of such notice, the Secretary may take action as authorized by said subsections (a) and (b) and recover from such owner or agent the reasonable costs of any care, handling, and disposal incurred by the Secretary in connection therewith. Such costs shall not constitute a lien against the animals, carcasses, products, or articles involved. Costs collected under this section shall be credited to the current appropriation for carrying out animal disease control activities of the Department.

(d) Compensation of owner; fair market value; payments from State or other source; availability of funds

Except as provided in subsection (e) of this section, the Secretary shall compensate the owner of any animal, carcass, product, or article destroyed pursuant to the provisions of this section. Such compensation shall be based upon the fair market value as determined by the Secretary, of any such animal, carcass, product, or article at the time of the destruction thereof. Compensation paid any owner under this subsection shall not exceed the difference between any compensation received by such owner from a State or other source and such fair market value of the animal, carcass, product, or article. Funds in the Treasury available for carrying out animal disease control activities of the Department of Agriculture shall be used for carrying out this subsection.

(e) Restriction on payment of compensation in cases of violation of law or regulation

No such payment shall be made by the Secretary for any animal, carcass, product, or article which has been moved or handled by the owner thereof or his agent knowingly in violation of a law or regulation administered by the Secretary for the prevention of the interstate dissemination of the communicable disease, for which the animal, carcass, product, or article was destroyed or a law or regulation for the enforcement of which the Secretary enters or has entered into a cooperative agreement for the con-

trol and eradication of such disease, or for any animal which has moved into the United States contrary to such law or regulation administered by the Secretary for the prevention of the introduction of a communicable disease of livestock or poultry.

(Pub. L. 87-518, § 2, July 2, 1962, 76 Stat. 129.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134e, 134f, 134g, 134h of this title; title 16 section 1540.

§ 134b. Regulations for clean and sanitary movement of animals

The Secretary, in order to protect the health of the livestock or poultry of the Nation, may promulgate regulations requiring that railway cars; vessels; airplanes; trucks; and other means of conveyance; stockyards; feed, water, and rest stations; and other facilities, used in connection with the movement of animals into or from the United States, or interstate, be maintained in a clean and sanitary condition, including requirements for inspection, cleaning, and disinfection.

(Pub. L. 87-518, § 3, July 2, 1962, 76 Stat. 130.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134e, 134f, 134g, 134h of this title; title 16 section 1540.

§ 134c. Regulations for movement of animals affected or exposed to communicable disease

The Secretary is authorized to promulgate regulations prohibiting or regulating the movement into the United States of any animals which are or have been affected with or exposed to any communicable animal disease, or which have been vaccinated or otherwise treated for any such disease, or which he finds would otherwise be likely to introduce or disseminate any such disease, when he determines that such action is necessary to protect the livestock or poultry of the United States.

(Pub. L. 87-518, § 4, July 2, 1962, 76 Stat. 130.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134e, 134f, 134g, 134h of this title; title 16 section 1540.

§ 134d. Inspections and seizures; issuance of warrants

Employees of the Department of Agriculture designated by the Secretary for the purpose, when properly identified, shall have authority (1) to stop and inspect, without a warrant, any person or means of conveyance, moving into the United States from a foreign country, to determine whether such person or means of conveyance is carrying any animal, carcass, product, or article regulated or subject to disposal under any law or regulation administered by the Secretary for prevention of the introduction or dissemination of any communicable animal disease; (2) to stop and inspect, without a warrant, any means of conveyance moving interstate upon probable cause to believe that such means of conveyance is carrying any animal, carcass, product, or article regulated or subject to disposal under any law or regulation administered by the Secretary for the prevention of the introduction or dissemination of any communicable animal disease; and (3) to enter upon, with a warrant, any premises for the purpose of making inspections and seizures necessary under such laws and regulations. Any Federal judge, or any judge of a court of record in the United States, or any United States commissioner, may, within his jurisdiction, upon proper oath or affirmation indicating probable cause to believe that there is on certain premises any animal, carcass, product, or article regulated or subject to disposal under any law or regulation administered by the Secretary for the prevention of the introduction or dissemination of any communicable animal disease, issue warrants for the entry upon such premises and for inspections and seizures necessary under such laws and regulations. Such warrants may be executed by any authorized employee of the Department of Agriculture.

(Pub. L. 87-518, § 5, July 2, 1962, 76 Stat. 130; Pub. L. 90-578, title IV, § 402, Oct. 17, 1968, 82 Stat. 1118.)

CHANGE OF NAME

United States commissioners were replaced by United States magistrates pursuant to Pub. L. 90-578, Oct. 17, 1968, 82 Stat. 1118. See chapter 43 (§ 631 et seq.) of Title 28, Judiciary and Judicial Procedure.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134e, 134f, 134g, 134h of this title; title 16 section 1540.

§ 134e. Penalties; enforcement provisions

(a) Whoever knowingly violates any regulation promulgated pursuant to the provisions of sections 134 through 134d of this title shall be punished by a fine not exceeding $1,000 or by imprisonment not exceeding one year, or both.

(b) The Secretary may bring an action to enjoin the violation of, or to compel compliance with, any regulation promulgated or order issued under said sections, or to enjoin any interference by any person with an employee of the Department of Agriculture in carrying out any duties under said sections, whenever the Secretary has reason to believe that such person has violated, or is about to violate, any such regulation or order, or has interfered, or is about to interfere, with any such employee. Such action shall be brought in the United States district court, or the United States court of any Territory or possession, for the judicial district in which such person resides or transacts business or in which the violation, omission, or interference has occurred or is about to occur. Process in such cases may be served in any judicial district wherein the defendant resides or transacts business or wherever the defendant may be found, and subpenas for witnesses who are required to attend the court in any judicial district in any such cases may run into any other judicial district.

(Pub. L. 87-518, § 6, July 2, 1962, 76 Stat. 131.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134f, 134g, 134h of this title; title 16 section 1540.

§ 134f. Promulgation of regulations

The Secretary is authorized to issue such regulations as he deems necessary to carry out the provisions of this Act.

(Pub. L. 87-518, § 11, July 2, 1962, 76 Stat. 132.)

REFERENCES IN TEXT

This Act, referred to in text, is Pub. L. 87-518, July 2, 1962, 76 Stat. 129, which enacted sections 134 to 134h of this title and amended sections 114a, 123 to 126, and 128 of this title and section 1114 of Title 18, Crimes and Criminal Procedure. For complete classification of this Act to the Code, see Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134g, 134h of this title; title 16 section 1540.

§ 134g. Authority in addition to other laws; repeal of inconsistent provisions

The authority conferred by this Act shall be in addition to authority conferred by other statutes. Any provision of any other Act inconsistent with the provisions of this Act is repealed.

(Pub. L. 87-518, § 12, July 2, 1962, 76 Stat. 132.)

REFERENCES IN TEXT

This Act, referred to in text, is Pub. L. 87-518, July 2, 1962, 76 Stat. 129, which enacted sections 134 to 134h of this title and amended sections 114a, 123 to 126, and 128 of this title and section 1114 of Title 18, Crimes and Criminal Procedure. For complete classification of this Act to the Code, see Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134f, 134h of this title; title 16 section 1540.

§ 134h. Separability of provisions

If any provision of this Act or application thereof to any person or circumstances is held invalid, the remainder of the Act and the application of such provision to other persons and circumstances shall not be affected thereby.

(Pub. L. 87-518, § 13, July 2, 1962, 76 Stat. 132.)

REFERENCES IN TEXT

This Act, referred to in text, is Pub. L. 87-518, July 2, 1962, 76 Stat. 129, which enacted sections 134 to 134h of this title and amended sections 114a, 123 to 126, and 128 of this title and section 1114 of Title 18, Crimes and Criminal Procedure. For complete classification of this Act to the Code, see Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 134, 134f, 134g of this title; title 16 section 1540.

§ 135. International animal quarantine station; establishment; acceptance of gifts; cooperation with breeders' organizations; collection of fees

The Secretary of Agriculture is authorized, in his discretion, to establish and maintain an international animal quarantine station within the territory of the United States. The quarantine station shall be located on an island selected by the Secretary of Agriculture where, in his judgment, maximum animal disease and pest security measures can be maintained. The Secretary of Agriculture is authorized to acquire land or any interest therein, by purchase, donation, exchange, or otherwise and construct or lease buildings, improvements, and other facilities as may be necessary for the establishment and maintenance of such quarantine station. The Secretary of Agriculture, on behalf of the United States, is authorized to accept any gift or donation of money, personal property, buildings, improvements, and other facilities for the purpose of conducting the functions authorized under sections 135 to 135b of this title. Notwithstanding the provisions of any other law to prevent the introduction or dissemination of livestock or poultry disease or pests, animals may be brought into the quarantine station from any country, including but not limited to those countries in which the Secretary of Agriculture determines that rinderpest or foot-and-mouth disease exists, and subsequently moved into other parts of the United States in accordance with such conditions as the Secretary of Agriculture shall determine are adequate in order to prevent the introduction into and the dissemination within the United States of livestock or poultry diseases or pests. The Secretary of Agriculture is authorized to cooperate in such manner as he deems appropriate, with other North American countries or with breeders' organizations or similar organizations or with individuals within the United States regarding importation of animals into and through the quarantine station and to charge and collect reasonable fees for use of the facilities of such station from importers. Such fees shall be deposited into the Treasury of the United States to the credit of the appropriation charged with the operating expenses of the quarantine station. The Secretary is authorized to issue such regulations as he deems necessary to carry out the provisions of sections 135 to 135b of this title.

(Pub. L. 91-239, § 1, May 6, 1970, 84 Stat. 202.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 135a, 135b of this title; title 16 section 1540.

§ 135a. Smuggling penalties

The provisions and penalties of section 545 of title 18 shall apply to the bringing of animals to the quarantine station or the subsequent movement of animals to other parts of the United States, including Puerto Rico, Guam, and the Virgin Islands, contrary to the conditions prescribed by the Secretary in regulations issued hereunder.

(Pub. L. 91-239, § 2, May 6, 1970, 84 Stat. 202.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 135, 135b of this title; title 16 section 1540.

§ 135b. Authorization of appropriations

There are hereby authorized to be appropriated such sums as are necessary to carry out the provisions of sections 135 to 135b of this title.

(Pub. L. 91-239, § 3, May 6, 1970, 84 Stat. 202.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 135, 135a of this title; title 16 section 1540.

SUBCHAPTER IV—IMPORTATION OF MILK AND CREAM

Federal Food, Drug, and Cosmetic Act

By virtue of act June 25, 1938, ch. 675, § 902(c), 52 Stat. 1059, nothing contained in section 301 et seq. of this title shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of this subchapter.

Subchapter Referred to in Other Sections

This subchapter is referred to in section 392 of this title.

§ 141. Prohibition of importation without permit

On and after May 16, 1927, the importation into the United States of milk and cream is prohibited unless the person by whom such milk or cream is shipped or transported into the United States holds a valid permit from the Secretary of Health, Education, and Welfare.

(Feb. 15, 1927, ch. 155, § 1, 44 Stat. 1101; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

Short Title

Act July 12, 1943, ch. 221, Title II, 57 Stat. 499, provided in part that act Feb. 15, 1927, which is classified to this subchapter, may be cited as "Import Milk Act".

Transfer of Functions

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

Cross References

Federal Food, Drug, and Cosmetic Act as not affecting, modifying, repealing, or superseding this subchapter, see section 392(b) of this title.

§ 142. Milk or cream when unfit for importation

Milk or cream shall be considered unfit for importation (1) when all cows producing such milk or cream are not healthy and a physical examination of all such cows has not been made within one year previous to such milk being offered for importation; (2) when such milk or cream, if raw, is not produced from cows which have passed a tuberculin test applied by a duly authorized official veterinarian of the United States, or of the country in which such milk or cream is produced, within one year previous to the time of the importation, showing that such cows are free from tuberculosis; (3) when the sanitary conditions of the dairy farm or plant in which such milk or cream is produced or handled do not score at least fifty points out of one hundred points according to the methods for scoring as provided by the score cards, used by the Bureau of Dairy Industry of the United States Department of Agriculture at the time such dairy farms or plants are scored; (4) in the case of raw milk if the number of bacteria per cubic centimeter exceeds three hundred thousand and in the case of raw cream seven hundred and fifty thousand, in the case of pasteurized milk if the number of bacteria per cubic centimeter exceeds one hundred thousand, and in the case of pasteurized cream five hundred thousand; (5) when the temperature of milk or cream at the time of importation exceeds fifty degrees Fahrenheit.

(Feb. 15, 1927, ch. 155, § 2, 44 Stat. 1101.)

Transfer of Functions

Agricultural Research Service became the successor to the functions of the Bureau of Dairy Industry under Secretary of Agriculture's Memorandum 1320, Supplement 4, Nov. 2, 1953.

Section Referred to in Other Sections

This section is referred to in section 143 of this title.

§ 143. Inspection; certified statement in lieu thereof; waiver of requirements of section 142; regulations; suspension and revocation of permits

The Secretary of Health, Education, and Welfare shall cause such inspections to be made as are necessary to insure that milk and cream are so produced and handled as to comply with the provisions of section 142 of this title, and in all cases when he finds that such milk and/or cream is produced and handled so as not to be unfit for importation under clauses 1, 2, and 3 of section 142 of this title, he shall issue to persons making application therefor permits to ship milk and/or cream into the United States: *Provided,* That in lieu of the inspections to be made by or under the direction of the Secretary he may, in his discretion, accept a duly certified statement signed by a duly accredited official of an authorized department of any foreign government and/or of any State of the United States or any municipality thereof that the provisions in clauses 1, 2, and 3 of section 142 of this title have been complied with. Such certificate of the accredited official of an authorized department of any foreign government shall be in the form prescribed by the Secretary, who is authorized and directed to prescribe such form as well as rules and regulations regulating the issuance of permits to import milk or cream into the United States.

The Secretary is authorized, in his discretion, to waive the requirement of clause 4 of section 142 of this title when issuing permits to operators of condenseries in which milk and/or cream is used when sterilization of the milk and/or cream is a necessary process: *Provided, however,* That no milk and/or cream shall be imported whose bacterial count per cubic centimeter in any event exceeds one million two hundred thousand: *Provided, further,* That such requirements shall not be waived unless the farm producing such milk to be imported is within a radius of fifteen miles of the condensery in which it is to be processed: *Provided further,* That if milk and/or cream imported when the requirements of clause 4 of section 142 of this title, have been so waived, is sold, used, or disposed of in its raw state or otherwise than as condensed milk by any person, the permit shall be revoked and the importer shall be subject to fine, imprisonment, or other penalty prescribed by this subchapter.

The Secretary is directed to waive the requirements of clauses 2 and 5 of section 142 of this title insofar as the same relate to milk when issuing permits to operators of, or to producers for delivery to, creameries and condensing plants in the United States within twenty

miles of the point of production of the milk, and who import no raw milk except for pasteurization or condensing: *Provided*, That if milk imported when the requirements of clauses 2 and 5 of section 142 of this title have been so waived is sold, used, or disposed of in its raw state, or otherwise than as pasteurized, condensed, or evaporated milk by any person, the permit shall be revoked and the importer shall be subjected to fine, imprisonment, or other penalty prescribed by this subchapter.

The Secretary is authorized and directed to make and enforce such regulations as may in his judgment be necessary to carry out the purpose of this subchapter for the handling of milk and cream, for the inspection of milk, cream, cows, barns, and other facilities used in the production and handling of milk and/or cream and the handling, keeping, transporting, and importing of milk and/or cream: *Provided, however*, That unless and until the Secretary shall provide for inspections to ascertain that clauses 1, 2, and 3 of section 142 of this title have been complied with, the Secretary shall issue temporary permits to any applicants therefor to ship or transport milk and/or cream into the United States.

The Secretary is authorized to suspend or revoke any permit for the shipment of milk or cream into the United States when he shall find that the holder thereof has failed to comply with the provisions of or has violated this subchapter or any of the regulations made hereunder, or that the milk and/or cream brought or shipped by the holder of such permit into the United States is not produced and handled in conformity with, or that the quality thereof does not conform to, all of the provisions of section 142 of this title.

(Feb. 15, 1927, ch. 155, § 3, 44 Stat. 1102; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

§ 144. Unlawful receiving of imported milk or cream

It shall be unlawful for any person in the United States to receive milk or cream imported into the United States unless the importation is in accordance with the provisions of this subchapter.

(Feb. 15, 1927, ch. 155, § 4, 44 Stat. 1103.)

§ 145. Penalties

Any person who knowingly violates any provision of this subchapter shall, in addition to all other penalties prescribed by law, be punished by a fine of not less than $50 nor more than $2,000, or by imprisonment for not more than one year, or by both such fine and imprisonment.

(Feb. 15, 1927, ch. 155, § 5, 44 Stat. 1103.)

§ 146. Authorization of appropriations

There is authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, the sum of $50,000 per annum, to enable the Secretary of Health, Education, and Welfare to carry out the provisions of this subchapter.

(Feb. 15, 1927, ch. 155, § 6, 44 Stat. 1103; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2421, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

§ 147. Repeal of inconsistent laws

Any laws or parts of laws inconsistent with this subchapter are repealed.

(Feb. 15, 1927, ch. 155, § 7, 44 Stat. 1103.)

CROSS REFERENCES

Federal Food, Drug, and Cosmetic Act as not affecting, modifying, repealing, or superseding this subchapter, see section 392(b) of this title.

§ 148. Powers of State with respect of milk or cream lawfully imported

Nothing in this subchapter is intended nor shall be construed to affect the powers of any State, or any political subdivision thereof, to regulate the shipment of milk or cream into, or the handling, sale, or other disposition of milk or cream in, such State or political subdivision after the milk and/or cream shall have been lawfully imported under the provisions of this subchapter.

(Feb. 15, 1927, ch. 155, § 8, 44 Stat. 1103.)

§ 149. Definitions; "person"; "United States"

When used in this subchapter—

(a) The term "person" means an individual, partnership, association, or corporation.

(b) The term "United States" means the fifty States and the District of Columbia.

(Feb. 15, 1927, ch. 155, § 9, 44 Stat. 1103; June 25, 1959, Pub. L. 86-70, § 19, 73 Stat. 145; July 12, 1960, Pub. L. 86-624, § 15, 74 Stat. 415.)

AMENDMENTS

1960—Subsec. (b). Pub. L. 86-624 substituted "means the fifty States and the District of Columbia" for "means continental United States, including Alaska".

1959—Subsec. (b). Pub. L. 86-70 inserted ", including Alaska" following "continental United States".

CHAPTER 5—VIRUSES, SERUMS, TOXINS, ANTITOXINS, AND ANALOGOUS PRODUCTS

Sec.
151. Preparation and sale of worthless or harmful products for domestic animals prohibited; preparation to be in compliance with rules at licensed establishments.
152. Importation regulated and prohibited.
153. Inspection of imports; denial of entry and destruction.
154. Regulations for preparation and sale; licenses.
155. Permits for importation.

Sec.
156. Licenses conditioned on permitting inspection; suspension of licenses.
157. Inspection.
158. Offenses; punishment.

CROSS REFERENCES

Biological products, regulation, see section 262 of Title 42, The Public Health and Welfare.

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in section 392 of this title; title 15 section 1459.

§ 151. Preparation and sale of worthless or harmful products for domestic animals prohibited; preparation to be in compliance with rules at licensed establishments

It shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange in the District of Columbia, or in the Territories, or in any place under the jurisdiction of the United States, or to ship or deliver for shipment from one State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture as hereinafter authorized.

(Mar. 4, 1913, ch. 145, 37 Stat. 832.)

CODIFICATION

This chapter constitutes the eighth paragraph under the heading "Bureau of Animal Industry," in the Department of Agriculture Appropriation Act, 1914.

SHORT TITLE

Act Mar. 4, 1913, ch. 145, 37 Stat. 832 [this chapter], is popularly known as the Virus-Serum-Toxin Act.

APPROPRIATIONS

An appropriation of $25,000 was made by act Mar. 4, 1913, for the purpose of carrying into effect these provisions. The appropriation for the fiscal year 1926 was by act Feb. 10, 1925, ch. 200, 43 Stat. 827.

§ 152. Importation regulated and prohibited

The importation into the United States, without a permit from the Secretary of Agriculture, of any virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and the importation of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, are prohibited.

(Mar. 4, 1913, ch. 145, 37 Stat. 832.)

§ 153. Inspection of imports; denial of entry and destruction

The Secretary of Agriculture is authorized to cause the Bureau of Animal Industry to examine and inspect all viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are being imported or offered for importation into the United States, to determine whether such viruses, serums, toxins, and analogous products are worthless, contaminated, dangerous, or harmful, and if it shall appear that any such virus, serum, toxin, or analogous product, for use in the treatment of domestic animals, is worthless, contaminated, dangerous, or harmful, the same shall be denied entry and shall be destroyed or returned at the expense of the owner or importer.

(Mar. 4, 1913, ch. 145, 37 Stat. 832.)

§ 154. Regulations for preparation and sale; licenses

The Secretary of Agriculture is authorized to make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and to issue, suspend, and revoke licenses for the maintenance of establishments for the preparation of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, intended for sale, barter, exchange, or shipment as aforesaid.

(Mar. 4, 1913, ch. 145, 37 Stat. 832.)

§ 155. Permits for importation

The Secretary of Agriculture is authorized to issue permits for the importation into the United States of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are not worthless, contaminated, dangerous, or harmful.

(Mar. 4, 1913, ch. 145, 37 Stat. 833.)

§ 156. Licenses conditioned on permitting inspection; suspension of licenses

All licenses issued under authority of this chapter to establishments where such viruses, serums, toxins, or analogous products are prepared for sale, barter, exchange, or shipment as aforesaid, shall be issued on condition that the licensee shall permit the inspection of such establishments and of such products and their preparation; and the Secretary of Agriculture may suspend or revoke any permit or license issued under authority of said chapter, after opportunity for hearing has been granted the licensee or importer, when the Secretary of Agriculture is satisfied that such license or permit is being used to facilitate or effect the preparation, sale, barter, exchange, or shipment as aforesaid, or the importation into the United States of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals.

(Mar. 4, 1913, ch. 145, 37 Stat. 833.)

REFERENCES IN TEXT

This chapter, referred to in text, was in the original "this Act", meaning act Mar. 4, 1913, ch. 145, 37 Stat. 828, which enacted this chapter, sections 155 and 393 of Title 7, Agriculture, section 316 of Title 15, Commerce and Trade, sections 501, 502, 512, 558, and 560 of Title 16, Conservation, and section 630 of Title 31, Money and Finance, and amended section 83 of former Title 5, Executive Departments and Government Officers and Employees, and sections 518 and 673 of Title 16.

Section 316 of Title 15 was omitted from the Code as superseded by section 5701 et seq. of Title 5, Government Organization and Employees. Section 83 of former Title 5 was repealed and reenacted as section 5946 of Title 5 by Pub. L. 89-554, Sept. J, 1966, 80 Stat. 514. For complete classification of act Mar. 4, 1913 to the Code, see Tables volume.

§ 157. Inspection

Any officer, agent, or employee of the Department of Agriculture duly authorized by the Secretary of Agriculture for the purpose may, at any hour during the daytime or nighttime, enter and inspect any establishment licensed under the provisions of this chapter where any virus, serum, toxin, or analogous product for use in the treatment of domestic animals is prepared for sale, barter, exchange, or shipment as aforesaid.

(Mar. 4, 1913, ch. 145, 37 Stat. 833.)

REFERENCES IN TEXT

This chapter, referred to in text, was in the original "this Act", meaning act Mar. 4, 1913, ch. 145, 37 Stat. 828, which enacted this chapter, sections 155 and 393 of Title 7, Agriculture, section 316 of Title 15, Commerce and Trade, sections 501, 502, 512, 558, and 560 of Title 16, Conservation, and section 630 of Title 31, Money and Finance, and amended section 83 of former Title 5, Executive Departments and Government Officers and Employees, and sections 518 and 673 of Title 16.

Section 316 of Title 15 was omitted from the Code as superseded by section 5701 et seq. of Title 5, Government Organization and Employees. Section 83 of former Title 5 was repealed and reenacted as section 5946 of Title 5 by Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 514. For complete classification of act Mar. 4, 1913 to the Code, see Tables volume.

CROSS REFERENCES

Overtime of employees working at establishments which prepare virus, serum, toxin and analogous products, see section 394a of Title 7, Agriculture.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 7 section 394a.

§ 158. Offenses; punishment

Any person, firm, or corporation who shall violate any of the provisions of this chapter shall be deemed guilty of a misdemeanor, and shall, upon conviction, be punished by a fine of not exceeding $1,000 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(Mar. 4, 1913, ch. 145, 37 Stat. 833.)

REFERENCES IN TEXT

This chapter, referred to in text, was in the original "this Act", meaning act Mar. 4, 1913, ch. 145, 37 Stat. 828, which enacted this chapter, sections 155 and 393 of Title 7, Agriculture, section 316 of Title 15, Commerce and Trade, sections 501, 502, 512, 558, and 560 of Title 16, Conservation, and section 630 of Title 31, Money and Finance, and amended section 83 of former Title 5, Executive Departments and Government Officers and Employees, and sections 518 and 673 of Title 16.

Section 316 of Title 15 was omitted from the Code as superseded by section 5701 et seq. of Title 5, Government Organization and Employees. Section 83 of former Title 5 was repealed and reenacted as section 5946 of Title 5 by Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 514. For complete classification of act Mar. 4, 1913 to the Code, see Tables volume.

CHAPTER 5A—BUREAU OF NARCOTICS

§§ 161 to 165. Omitted

CODIFICATION

Section 161, acts June 14, 1930, ch. 488, § 1, 46 Stat. 585; Oct. 15, 1949, ch. 695, § 6(a), 63 Stat. 881, established a Bureau of Narcotics in the Department of the Treasury and provided for appointment of a Commissioner of Narcotics for the Bureau with duty of making an annual report to Congress.

Section 162, acts June 14, 1930, ch. 488, § 2, 46 Stat. 585; June 26, 1930, ch. 623, § 1, 46 Stat. 819; Oct. 27, 1970, Pub. L. 91-513, title III, § 1101(a)(4), 84 Stat. 1291, provided for appointment and compensation of a deputy commissioner and other personnel for the Bureau of Narcotics, required the deputy to be an acting Commissioner during absence or disability of the Commissioner or a vacancy in the office, and authorized designation of a member of the Treasury Department as an acting Commissioner in event there is no Commissioner or deputy commissioner.

Section 163, act Mar. 3, 1927, ch. 348, § 4(a), 44 Stat. 1382, provided for transfer of control of narcotic drugs to the Secretary of the Treasury from the Commissioner of Internal Revenue and his assistants, agents, and inspectors.

Section 164, acts June 14, 1930, ch. 488, § 3, 46 Stat. 586; June 26, 1930, ch. 623, § 2, 46 Stat. 819; Ex. Ord. No. 6639, Mar. 10, 1934, abolished the Federal Narcotics Control Board and transferred powers of such Board to the Commissioner of Narcotics, authorized the Secretary of the Treasury to confer or impose his duties under section 163 of this title upon the Commissioner or other personnel of the Bureau of Narcotics, continued in effect orders, rules, and regulations in existence on July 1, 1930, until modified, superseded, or repealed by the Commissioner, with approval of the Secretary of the Treasury, and provided for determination before such Bureau of Narcotics of proceedings, investigations, and other matters pending on July 1, 1930 before Bureau of Prohibition or Federal Narcotics Control Board respecting narcotic drug law administration or enforcement. Bureau of Prohibition personnel, records, property, and unexpended balances of appropriations were previously transferred to Bureau of Narcotics as were powers of the Attorney General respecting the Bureau of Prohibition to the Commissioner of Internal Revenue.

Section 165, act June 14, 1930, ch. 488, § 5, 46 Stat. 587, provided for review of decisions of Commissioner of Narcotics by the Secretary of the Treasury.

TRANSFER OF FUNCTIONS

Functions of the Secretary of the Treasury administered through or respecting the Bureau of Narcotics and all functions of the Bureau, the Commissioner of Narcotics, and the officers, employees and agencies of the Bureau were transferred to the Attorney General and the Bureau and the office of Commissioner of Narcotics were abolished by Reorg. Plan No. 1 of 1968, eff. Apr. 8, 1968, 33 F.R. 5611, 82 Stat. 1367, set out in the Appendix to Title 5, Government Organization and Employees. All positions, personnel, property, records, and unexpended balances of appropriations, allocations, and other funds of the Bureau and the Treasury Department, in connection with functions

transferred under this reorganization plan, were transferred to the Justice Department.

The Bureau of Narcotics and Dangerous Drugs, including the office of Director thereof, in the Department of Justice was abolished by Reorg. Plan No. 2 of 1973, eff. July 1, 1973, 38 F.R. 15932, 87 Stat. 1091, set out in the Appendix to Title 5, Government Organization and Employees. Reorg. Plan No. 2 of 1973 also created in the Department of Justice a single, comprehensive agency for the enforcement of drug laws to be known as the Drug Enforcement Administration, empowered the Attorney General to authorize the performance by officers, employees, and agencies of the Department of functions transferred to him, and directed the Attorney General to coordinate all drug law enforcement functions to assure maximum cooperation between the Drug Enforcement Administration, the Federal Bureau of Investigation, and the other units of the Department of Justice involved in drug law enforcement.

CHAPTER 6—NARCOTIC DRUGS

Executive Order No. 10302

Ex. Ord. No. 10302, Nov. 5, 1951, 16 F.R. 11257, formerly set out as a note preceding section 171, which established the Interdepartmental Committee on Narcotics, was revoked by Ex. Ord. No. 11529, Apr. 24, 1970, 35 F.R. 6697.

IMPORTATION OR EXPORTATION

§§ 171 to 174. Repealed. Pub. L. 91-513, title III, § 1101(a)(2), (4), Oct. 27, 1970, 84 Stat. 1291

Section 171, acts Feb. 9, 1909, ch. 100, § 1, 35 Stat. 614; Jan. 17, 1914, ch. 9, 38 Stat. 275; May 26, 1922, ch. 202, § 1, 42 Stat. 596; June 14, 1930, ch. 488, § 3, 46 Stat. 586; July 1, 1944, ch. 377, § 8, 58 Stat. 721; Mar. 8, 1946, ch. 81, § 7, 60 Stat. 39; Aug. 8, 1953, ch. 394, § 8, 67 Stat. 506, defined the terms narcotic drug, United States, and person. See section 801 et seq. of this title.

Section 172, acts Feb. 9, 1909, ch. 100, § 2(a) 35 Stat. 614; Jan. 17, 1914, ch. 9, 38 Stat. 275; June 7, 1924, ch. 352, 432 Stat. 657, established a Federal Narcotics Control Board. Act May 26, 1922, ch. 202, § 1, 42 Stat. 596, also classified to this section, was repealed by Pub. L. 89-554, § 8(a), Sept. 6, 1966, 80 Stat. 645.

Section 173, acts Feb. 9, 1909, ch. 100, § 2(b), (d), 35 Stat. 614; Jan. 17, 1914, ch. 9, 38 Stat. 275; May 26, 1922, ch. 202, § 1, 42 Stat. 596; June 7, 1924, ch. 352, 43 Stat. 657; June 14, 1930, ch. 488, § 3, 46 Stat. 586, prohibited the importation of narcotic drugs. See section 801 et seq. of this title.

Section 173a, act June 14, 1930, ch. 488, § 6, 46 Stat. 587, provided for the importation of additional amounts of coca leaves.

Section 174, acts Feb. 9, 1909, ch. 100, § 2(c), (f), 35 Stat. 614; Jan. 17, 1914, ch. 9, 38 Stat. 275; May 26, 1922, ch. 202, § 1, 42 Stat. 596; June 7, 1924, ch. 352, 43 Stat. 657; Nov. 2, 1951, ch. 666, §§ 1, 5(1), 65 Stat. 767; July 18, 1956, ch. 629, title I, § 105, 70 Stat. 570, set penalties for the bringing narcotic drugs into the United States contrary to law. See chapter 13 of this title.

Effective Date of Repeal

Repeal of sections by Pub. L. 91-513 effective on the first day of the seventh calendar month that begins after Oct. 27, 1970, see section 1105(a) of Pub. L. 91-513, set out as an Effective Date note under section 951 of this title.

Savings Provision

Section 1103 of Pub. L. 91-513 provided that:

"(a) Prosecutions for any violation of law occurring prior to the effective date of section 1101 [the first day of the seventh calendar month that begins after Oct. 26, 1970] shall not be affected by the repeals or amendments made by such section or section 1102 [repealing sections 171, to 174, 176 to 185, 188 to 188n, 191 to 193, 197, 198, 199, 501 to 517 of this title, sections 1401 to 1407, and 3616 of Title 18, Crimes and Criminal Procedure, sections 4701 to 4707, 4711 to 4716, 4721 to 4726, 4731 to 4736, 4741 to 4746, 4751 to 4757, 4761, 4762, 4771 to 4776, 7237, 7238, and 7491 of Title 26, Internal Revenue Code, sections 529a and 529g of Title 31, Money and Finance, section 1421m of Title 48, Territories and Insular Possessions, and amending section 162 of this title and sections 4251 of Title 18, 1584 of Title 19, Customs Duties, sections 4901, 4905, 6808, 7012, 7103, 7236, 7607, 7609, 7641, 7651, and 7655 of Title 26, section 2901 of Title 28, Judiciary and Judicial Procedure, sections 529d, 529e, 529f, and 1034 of Title 31, section 304m of Title 40, Public Buildings, Property, and Works, sections 3411 of Title 42, The Public Health and Welfare, section 239a of Title 46, Shipping, and section 787 of Title 49, Transportation], or abated by reason thereof.

"(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of section 1101 [the first day of the seventh calendar month that begins after Oct. 26, 1970] shall not be affected by the repeals or amendments made by such section or section 1102 [repealing this section and sections 172 to 174, 176 to 185, 188 to 188n, 191 to 193, 197, 198, 199, 501 to 517 of this title, sections 1401 to 1407 and 3616 of Title 18, Crimes and Criminal Procedure, sections 4701, 4707, 4711 to 4716, 4721 to 4726, 4731 to 4736, 4741 to 4746, 4751 to 4757, 4761, 4762, 4771 to 4776, 7237, 7238, and 7491 of Title 26, Internal Revenue Code, sections 529a and 529g of Title 31, Money and Finance, section 1421m of Title 48, Territories and Insular Possessions, and amending section 162 of this title and sections 4251 of Title 18, 1584 of Title 19, Customs Duties, sections 4901, 4905, 6808, 7012, 7103, 7326, 7607, 7609, 7641, 7651, and 7655 of Title 26, section 2901 of Title 28, Judiciary and Judicial Procedure, sections 529d, 529e, 529f, and 1034 of title 31, section 304m of Title 40, Public Buildings, Property, and Works, section 3411 of Title 42, The Public Health and Welfare, section 239a of Title 46, Shipping, and section 787 of Title 49, Transportation], or abated by reason thereof."

§ 175. Repealed. June 27, 1952, ch. 477, title IV, § 403(a)(10), 66 Stat. 279

Section, acts Feb. 9, 1909, ch. 100, § 2(e), 35 Stat. 614; Jan. 17, 1914, ch. 9, 38 Stat. 275; May 26, 1922, ch. 202, § 1, 42 Stat. 596; June 7, 1924, ch. 352, 43 Stat. 657, related to deportation of convicted aliens, and is now covered by section 1251 et seq. of Title 8, Aliens and Nationality.

§§ 176 to 185. Repealed. Pub. L. 91-513, title III, § 1101(a)(2), (9), Oct. 27, 1970, 84 Stat. 1291, 1292

Section 176, acts Feb. 9, 1909, ch. 100, § 2(g), 35 Stat. 614; Jan. 17, 1914, ch. 9, 38 Stat. 275; May 26, 1922, ch. 202 § 1, 42 Stat. 596; June 7, 1924, ch. 352, 43 Stat. 657, covered the liability of masters of vessels and persons in charge of railroad cars and other vehicles used to carry narcotic drugs.

Section 176a, act Feb. 9, 1909, ch. 100, § 2(h), as added July 18, 1956, ch. 629, title I, § 106, 70 Stat. 570, covered the illegal importation of marihuana and set penalties for such illegal importation. See section 801 et seq. of this title.

Section 176b, act Feb. 9, 1909, ch. 100, § 2(i), as added July 18, 1956, ch. 629, title I, § 107, 70 Stat. 571, prohibited the sale of heroin to juveniles and set penalties for such illegal sale. See section 801 et seq. of this title.

Section 177, acts Feb. 9, 1909, ch. 100, § 2(a), 35 Stat. 614; Jan. 17, 1914, ch. 9, 38 Stat. 275; May 26, 1922, ch. 202, § 1, 42 Stat. 596; June 7, 1924, ch. 352, 43 Stat. 657, vested the administration of the Narcotic Drugs Import and Export Act in the Department of the Treasury.

Section 178, act Feb. 9, 1909, ch. 100, § 4, as added Jan. 17, 1914, ch. 9, 38 Stat. 275, prohibited the posses-

sion of smoking opium. See section 801 et seq. of this title.

Section 179, act Feb. 9, 1909, ch. 100, § 4, as added Jan. 17, 1914, ch. 9, 38 Stat. 275, covered the liability of masters of vessels and persons in charge of railroad cars or other vehicles for possession of smoking heroin. See section 801 et seq. of this title.

Section 180, act Feb. 9, 1909, ch. 100, § 5, as added Jan. 17, 1914, ch. 9, 38 Stat. 275, and amended May 26, 1922, ch. 202, § 2, 42 Stat. 597; June 14, 1930, ch. 488, § 3, 46 Stat. 586, prohibited the admission of smoking opium even for transportation to another country or for transferral from one vessel to another.

Section 181, act Feb. 9, 1909, ch. 100, § 3, as added Jan. 17, 1914, ch. 9, 38 Stat. 275, created a presumption of illegal importation based upon presence of smoking opium in the United States.

Section 182, act Feb. 9, 1909, ch. 100, § 6, as added Jan. 17, 1914, ch. 9, 348 Stat. 275, and amended May 26, 1922, ch. 202, § 2, 42 Stat. 597; June 14, 1930, ch. 488, § 3, 46 Stat. 586; Apr. 22, 1960, Pub. L. 86-429, § 15, 74 Stat. 66, forbade the exportation of narcotic drugs. See section 801 et seq. of this title.

Section 183, act Feb. 9, 1909, ch. 100, § 7, as added Jan. 17, 1914, ch. 9, 38 Stat. 277, set out the penalties for the illegal exportation of narcotic drugs.

Section 184, act Feb. 9, 1909, ch. 100, § 8, as added Jan. 17, 1914, ch. 9, 38 Stat. 277, and amended May 26, 1922, ch. 202, § 3, 42 Stat. 598, provided for the seizure and forfeiture of narcotic drugs found on vessels and not shown on the manifest or landed from vessels without a permit.

Section 184a, acts July 11, 1941, ch. 289, § 1, 55 Stat. 584; July 18, 1956, ch. 629, title I, § 108, 70 Stat. 571, made illegal the bringing on board a vessel of the United States any narcotic drugs not constituting a part of the cargo.

Section 185, act Feb. 9, 1909, ch. 100, § 9, as added May 26, 1922, ch. 202, § 4, 42 Stat. 598, authorized the citation of act Feb. 9, 1909, ch. 100, as the "Narcotic Drugs Import and Export Act".

EFFECTIVE DATE OF REPEAL

Repeal of sections by Pub. L. 91-513 effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, see section 1105(a) of Pub. L. 91-513, set out as an Effective Date note under section 951 of this title.

SAVINGS PROVISION

Prosecutions for any violation of law occurring, and civil seizures or forfeitures and injunctive proceedings commenced, prior to the effective date of repeal of these sections by section 1101 of Pub. L. 91-513 not to be affected or abated by reason thereof, see section 1103 of Pub. L. 91-513, set out as a Savings Provision note under sections 171 to 174 of this title.

MARIHUANA AND HEALTH REPORTING

§§ 186, 187. Transferred

CODIFICATION

Section 186, Pub. L. 91-296, title V, § 501, June 30, 1970, 84 Stat. 352, which related to congressional findings as to marihuana use, the need for a better understanding of the health consequences, and the lack of information thereto, was transferred and set out as a note under section 242 of Title 42, The Public Health and Welfare.

Section 187, Pub. L. 91-296, title V, § 502, June 30, 1970, 84 Stat. 352, which directed the Secretary of Health, Education and Welfare to report to Congress on the current information on the health consequence of marihuana use, with recommendations for legislative and administrative action and to submit a preliminary report no later than 90 days after June 30, 1970, was transferred and set out as a note under section 242 of Title 42, The Public Health and Welfare.

DOMESTIC CONTROL OF PRODUCTION AND DISTRIBUTION OF THE OPIUM POPPY

§§ 188 to 188n. Repealed. Pub. L. 91-513, title III, § 1101(a)(7), Oct. 27, 1970, 84 Stat. 1292

Sections, acts Dec. 11, 1942, ch. 720, 56 Stat. 1045; June 25, 1959, Pub. 86-70, § 20, 73 Stat. 145; July 12, 1960, Pub. L. 86-624, § 16, 74 Stat. 415, known as the "Opium Poppy Control Act of 1942", provided for the domestic control of production and distribution of the opium poppy. Sections 1-17 of said Act of Dec. 11, 1942, were classified, respectively, to sections 188, 188 notes, and 188a to 188n of this title.

EFFECTIVE DATE OF REPEAL

Repeal of sections by Pub. L. 91-513 effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, see section 1105(a) of Pub. L. 91-513, set out as an Effective Date note under section 951 of this title.

SAVINGS PROVISION

Prosecutions for any violation of law occurring, and civil seizures or forfeitures and injunctive proceedings commenced, prior to the effective date of repeal of these sections by section 1101 of Pub. L. 91-513 not to be affected or abated by reason thereof, see section 1103 of Pub. L. 91-513, set out as a Savings Provision note under section 171 of this title.

IMPORTATION BY CHINESE SUBJECTS OR TRAFFICKING IN, IN CHINA, BY UNITED STATES CITIZENS

§§ 191 to 193. Repealed. Pub. L. 91-513, title III, § 1101(a)(1), Oct. 27, 1970, 84 Stat. 1291

Sections, acts Feb. 23, 1887, ch. 210, 24 Stat. 409; June 25, 1948, ch. 646, §§ 5, 39, 62 Stat. 986, 992, prohibited the importation of opium by Chinese subjects and the trafficking in, in China, of opium by United States citizens. Sections 1 to 3 of said Act of Feb. 23, 1887, were classified to sections 191 to 193, respectively, of this title.

EFFECTIVE DATE OF REPEAL

Repeal of sections by Pub. L. 91-513 effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, see section 1105(a) of Pub. L. 91-513, set out as an Effective Date note under section 951 of this title.

SAVINGS PROVISION

Prosecutions for any violation of law occurring, and civil seizures or forfeitures and injunctive proceedings commenced, prior to the effective date of repeal of these sections by section 1101 of Pub. L. 91-513 not to be affected or abated by reason thereof, see section 1103 of Pub. L. 91-513, set out as a Savings Provision note under section 171 of this title.

MISCELLANEOUS

§ 196. Repealed. July 1, 1944, ch. 373, title XIII, § 1313, 58 Stat. 714

Section, act June 14, 1930, ch. 488, § 4(b), (c), 46 Stat. 587; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, related to studies and investigations by Surgeon General of the Public Health Service and is now covered by section 242 of Title 42, The Public Health and Welfare.

RENUMBERING OF REPEALING ACT

Section 611 of act July 1, 1944, which repealed this section, was renumbered 711 by act Aug. 13, 1946, ch. 958, § 5, 60 Stat. 1049, 713 by act Feb. 28, 1948, ch. 83, § 9(b), 62 Stat. 47, 813 by act July 30, 1956, ch. 779,

§ 3(b), 70 Stat. 720, 913 by Pub. L. 88-581, § 4(b), Sept. 4, 1964, 78 Stat. 919, 1013 by Pub. L. 89-239, § 3(b), Oct. 6, 1965, 79 Stat. 931, 1113 by Pub. L. 91-572, § 6(b), Dec. 24, 1970, 84 Stat. 1506, 1213 by Pub. L. 92-294, § 3(b), May 16, 1972, 86 Stat. 137, 1313 by Pub. L. 93-154, § 2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93-222, § 7(b), Dec. 29, 1973, 87 Stat. 936.

§§ 197, 198. Repealed. Pub. L. 91-513, title III, § 1101(a)(4), Oct. 27, 1970, 84 Stat. 1291

Section 197, act June 14, 1930, ch. 488, § 7, 46 Stat. 587, directed the Secretary of the Treasury to cooperate with the Secretary of State in the discharge of the international obligations of the United States concerning the traffic in narcotic drugs.

Section 198, acts June 14, 1930, ch. 488, § 8, 46 Stat. 587; July 18, 1956, ch. 629, title III, § 302, 70 Stat. 575, directed the Secretary of the Treasury to cooperate with the several states in the suppression of the abuse of narcotic drugs in their respective jurisdictions.

EFFECTIVE DATE OF REPEAL

Repeal of sections by Pub. L. 91-513 effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, see section 1105(a) of Pub. L. 91-513, set out as an Effective Date note under section 951 of this title.

SAVINGS PROVISION

Prosecutions for any violation of law occurring, and civil seizures or forfeitures and injunctive proceedings commenced, prior to the effective date of repeal of these sections by section 1101 of Pub. L. 91-513 not to be affected or abated by reason thereof, see section 1103 of Pub. L. 91-513, set out as a Savings Provision note under sections 171 to 174 of this title.

§§ 198a to 198c. Transferred

CODIFICATION

Section 198a, act Aug. 11, 1955, ch. 800, § 1, 69 Stat. 684; Oct. 27, 1970, Pub. L. 91-513, title III, § 1102(t), 84 Stat. 1294, which related to the authority of the Secretary of the Treasury to issue subpenas, administer oaths and compel attendance of witnesses for the purpose of any investigation, was transferred to section 1034 of Title 31, Money and Finance.

Section 198b, act Aug. 11, 1955, ch. 800, § 2, 69 Stat. 685, which related to service of subpenas and proof of service, was transferred to section 1035 of Title 31, Money and Finance.

Section 198c, act Aug. 11, 1955, ch. 800, § 3, 69 Stat. 685, which related to contempt proceedings, was transferred to section 1036 of Title 31, Money and Finance.

§ 199. Repealed. Pub. L. 91-513, title III, § 1101(a)(5), Oct. 27, 1970, 84 Stat. 1292

Section, act July 3, 1930, ch. 829, 46 Stat. 850, authorized payment to persons giving information concerning violations of narcotics laws. See section 886(a) of this title.

EFFECTIVE DATE OF REPEAL

Repeal of section by Pub. L. 91-513 effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, see section 1105(a) of Pub. L. 91-513, set out as an Effective Date note under section 951 of this title.

SAVINGS PROVISION

Prosecutions for any violation of law occurring, and civil seizures or forfeitures and injunctive proceedings commenced, prior to the effective date of repeal of this section by section 1101 of Pub. L. 91-513 not to be affected or abated by reason thereof, see section 1103 of Pub. L. 91-513, set out as a Savings Provision note under section 171 of this title.

§§ 200 to 200b. Repealed. Nov. 2, 1951, ch. 666, § 5(2), 65 Stat. 769

Sections, acts Aug. 12, 1937, ch. 598, §§ 1 to 3, 50 Stat. 627; July 1, 1944, ch. 377, § 9, 58 Stat. 721; Mar. 8, 1946, ch. 81, § 8, 60 Stat. 39, related to punishment for offenses after first offense. See section 801 et seq. of this title.

SAVINGS CLAUSE

Section 6 of act Nov. 2, 1951, provided that any rights or liabilities now existing under former sections 200 to 200b of this title should not be affected by their repeal.

CHAPTER 7—PRACTICE OF PHARMACY AND SALE OF POISONS IN CONSULAR DISTRICTS IN CHINA

Sec.
201. Doing business without a license unlawful; employment of Chinese subjects.
202. Certain classes of persons and corporations excepted; insecticides.
203. Application for license; requirements; qualifications for license.
204. Issuance of license.
205. Display of license in pharmacy.
206. Revocation of license.
207. Restrictions on sales; written orders or prescriptions.
208. Certain preparations and sales excepted.
209. Poisons; book entry of sale; labels.
210. Pharmacist; unauthorized use of title.
211. Preservation of originals of prescriptions compounded and copies thereof; inspection of prescriptions by consular officers; marking containers of drugs.
212. Offenses; punishment; duty to enforce provisions.
213. Fraudulent representations to evade or defeat restrictions.
214. Previous laws unaffected.
215. "Consul" defined.

§ 201. Doing business without a license unlawful; employment of Chinese subjects

It shall be unlawful in the consular districts of the United States in China for any person whose permanent allegiance is due to the United States not licensed as a pharmacist within the meaning of this chapter to conduct or manage any pharmacy, drug or chemical store, apothecary shop, or other place of business for the retailing, compounding, or dispensing of any drugs, chemicals, or poisons, or for the compounding of physicians' prescriptions, or to keep exposed for sale at retail, any drugs, chemicals, or poisons, except as hereinafter provided, or, except as hereinafter provided, for any person whose permanent allegiance is due to the United States not licensed as a pharmacist within the meaning of this chapter to compound, dispense, or sell, at retail, any drug, chemical, poison, or pharmaceutical preparation upon the prescription of a physician, or otherwise, or to compound physicians' prescriptions, except as an aid to and under the proper supervision of a pharmacist licensed under this chapter. And it shall be unlawful for any person, firm, or corporation owing permanent allegiance to the United States owning partly or wholly or managing a pharmacy, drug store, or other place of business to cause or permit any person other than a licensed pharmacist to compound, dispense, or sell at retail any drug, medicine, or poison, except as an aid to and under the proper supervision of a licensed

pharmacist. Where it is necessary for a person, firm, or corporation whose permanent allegiance is due to the United States and owning partly or wholly or managing a pharmacy, drug store, or other place of business to employ Chinese subjects to compound, dispense, or sell at retail any drug, medicine, or poison, such person, firm, or corporation, owner, part owner, or manager of a pharmacy, drug store, or other place of business may employ such Chinese subjects when their character, ability, and age of twenty-one years or over have been certified to by at least two recognized and reputable practitioners of medicine, or two pharmacists licensed under this chapter whose permanent allegiance is due to the United States.

(Mar. 3, 1915, ch. 74, § 1, 38 Stat. 817.)

CODIFICATION

Section is comprised of part of section 1 of act Mar. 3, 1915. Remainder of such section 1 is classified to section 202 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 202 of this title.

§ 202. Certain classes of persons and corporations excepted; insecticides

Nothing in section 201 of this title shall be construed to interfere with any recognized and reputable practitioner of medicine, dentistry, or veterinary surgery in the compounding of his own prescriptions, or to prevent him from supplying to his patients such medicines as he may deem proper, except as hereinafter provided; nor with the exclusively wholesale business of any person, firm, or corporation whose permanent allegiance is due to the United States dealing and licensed as pharmacists, or having in their employ at least one person who is so licensed, except as hereinafter provided; nor with the sale by persons, firms, or corporations whose permanent allegiance is due to the United States other than pharmacists of poisonous substances sold exclusively for use in the arts, or as insecticides, when such substances are sold in unbroken packages bearing labels having plainly printed upon them the name of the contents, the word "Poison", when practicable the name of at least one suitable antidote, and the name and address of the vender.

(Mar. 3, 1915, ch. 74, § 1, 38 Stat. 817.)

CODIFICATION

Section is comprised of part of section 1 of act Mar. 3, 1915. Remainder of such section 1 is classified to section 201 of this title.

§ 203. Application for license; requirements; qualifications for license

Every person whose permanent allegiance is due to the United States desiring to practice as a pharmacist in the consular districts in China shall file with the consul an application, duly verified under oath, setting forth the name and age of the applicant, the place or places at which he pursued and the time spent in the study of pharmacy, the experience which the applicant has had in compounding physicians' prescriptions under the direction of a licensed pharmacist, and the name and location of the school or college of pharmacy, if any, of which he is a graduate, and shall submit evidence sufficient to show to the satisfaction of said consul that he is of good moral character and not addicted to the use of alcoholic liquors or narcotic drugs so as to render him unfit to practice pharmacy. Applicants shall be not less than twenty-one years of age and shall have had at least four years' experience in the practice of pharmacy or shall have served three years under the instruction of a regularly licensed pharmacist, and any applicant who has been graduated from a school or college of pharmacy recognized by the proper board of his State, Territory, District of Columbia, or other possession of the United States as in good standing shall be entitled to practice upon presentation of his diploma.

(Mar. 3, 1915, ch. 74, § 2, 38 Stat. 818.)

CODIFICATION

The words "now practicing as a pharmacist or," which preceded the words "desiring to practice" in the original text of this section, were omitted as obsolete.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 204 of this title.

§ 204. Issuance of license

If the applicant for license as a pharmacist has complied with the requirements of section 203 of this title, the consul shall issue to him a license which shall entitle him to practice pharmacy in the consular districts of the United States in China, subject to the provisions of this chapter.

(Mar. 3, 1915, ch. 74, § 3, 38 Stat. 819.)

§ 205. Display of license in pharmacy

Every license to practice pharmacy shall be conspicuously displayed by the person to whom the same has been issued in the pharmacy, drug store, or place of business, if any, of which the said person is the owner or part owner or manager.

(Mar. 3, 1915, ch. 74, § 5, 38 Stat. 819.)

§ 206. Revocation of license

The license of any person whose permanent allegiance is due to the United States to practice pharmacy in the consular districts of the United States in China may be revoked by the consul if such person be found to have obtained such license by fraud, or be addicted to the use of any narcotic or stimulant, or to be suffering from physical or mental disease, in such manner and to such extent as to render it expedient that in the interests of the public his license be canceled; or to be of an immoral character; or if such person be convicted in any court of competent jurisdiction of any offense involving moral turpitude. It shall be the duty of the consul to investigate any case in which it is discovered by him or made to appear to his satisfaction that any license issued under the provisions of this chapter is revocable and shall, after full hearing, if in his judgment the facts warrant it, revoke such license.

(Mar. 3, 1915, ch. 74, § 4, 38 Stat. 819.)

§ 207. Restrictions on sales; written orders or prescriptions

It shall be unlawful for any person, firm, or corporation whose permanent allegiance is due to the United States, either personally or by servant or agent or as the servant or agent of any other person or of any firm or corporation, to sell, furnish, or give away any cocaine, salts of cocaine, or preparation containing cocaine or salts of cocaine, or morphine or preparation containing morphine or salts of morphine, or any opium or preparation containing opium, or any chloral hydrate or preparation containing chloral hydrate, except upon the original written order or prescription of a recognized and reputable practitioner of medicine, dentistry, or veterinary medicine, which order or prescription shall be dated and shall contain the name of the person for whom prescribed, or, if ordered by a practitioner of veterinary medicine, shall state the kind of animal for which ordered and shall be signed by the person giving the order or prescription. Such order or prescription shall be, for a period of three years, retained on file by the person, firm, or corporation who compounds or dispenses the article ordered or prescribed, and it shall not be compounded or dispensed after the first time except upon the written order of the original prescriber.

(Mar. 3, 1915, ch. 74, § 6, 38 Stat. 819.)

CODIFICATION

Section is comprised of part of section 6 of act Mar. 3, 1915. Remainder of such section 6 is classified to section 208 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 208, 211 of this title.

§ 208. Certain preparations and sales excepted

The provisions of section 207 of this title shall not apply to preparations containing not more than two grains of opium or not more than one-quarter grain of morphine, or not more than one-quarter grain of cocaine, or not more than two grains of chloral hydrate in the fluid ounce, or, of a solid preparation, in one avoirdupois ounce, nor shall they apply to preparations sold in good faith for diarrhea and cholera, each bottle or package of which is accompanied by specific directions for use and caution against habitual use, nor to liniments or ointments sold in good faith as such when plainly labeled "for external use only", nor to powder of ipecac and opium, commonly known as Dover's powder, when sold in quantities not exceeding twenty grains. The provisions of this section or section 207 of this title shall not be construed to permit the selling, furnishing, giving away, or prescribing for the use of any habitual users of the same any cocaine, salts of cocaine, or preparation containing cocaine or salts of cocaine, or morphine or salts of morphine, or preparations containing morphine or salts of morphine, or any opium or preparation containing opium, or any chloral hydrate or preparation containing chloral hydrate. But the preceding sentence shall not be construed to prevent any recognized or reputable practitioner of medicine whose permanent allegiance is due to the United States from furnishing in good faith for the use of any habitual user of narcotic drugs who is under his professional care such substances as he may deem necessary for their treatment, when such prescriptions are not given or substances furnished for the purpose of evading the provisions of this section. But the provisions of this section or section 207 of this title shall not apply to sales at wholesale between jobbers, manufacturers, and retail druggists, hospitals, and scientific or public institutions.

(Mar. 3, 1915, ch. 74, § 6, 38 Stat. 819.)

CODIFICATION

Section is comprised of section 6 of act Mar. 3, 1915. Remainder of such section 6 is classified to section 207 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 211 of this title.

§ 209. Poisons; book entry of sale; labels

It shall be unlawful for any person, firm, or corporation whose permanent allegiance is due to the United States to sell or deliver to any other person any of the following-described substances, or any poisonous compound, combination, or preparation thereof, to wit: The compounds of and salts of antimony, arsenic, barium, chromium, copper, gold, lead, mercury, silver, and zinc, the caustic hydrates of sodium and potassium, solution or water of ammonia, methyl alcohol, paregoric, the concentrated mineral acids, oxalic and hydrocyanic acids and their salts, yellow phosphorus, Paris green, carbolic acid, the essential oils of almonds, pennyroyal, tansy, rue, and savin; croton oil, creosote, chloroform, cantharides, or aconite, belladonna, bitter almonds, colchicum, cotton root, cocculus indicus, conium, cannabis indica, digitalis, ergot, hyoscyamus, ignatia, lobelia, nux vomica, physostigma, phytolacca, strophanthus, stramonium, veratrum viride, or any of the poisonous alkaloids or alkaloidal salts derived from the foregoing, or any other poisonous alkaloids or their salts, or any other virulent poison, except in the manner following, and, moreover, if the applicant be less than eighteen years of age, except upon the written order of a person known or believed to be an adult.

It shall first be learned, by due inquiry, that the person to whom delivery is about to be made is aware of the poisonous character of the substance and that it is desired for a lawful purpose, and the box, bottle, or other package shall be plainly labeled with the name of the substance, the word "Poison", the name of at least one suitable antidote, when practicable, and the name and address of the person, firm, or corporation dispensing the substance. And before delivery be made of any of the foregoing substances, excepting solution or water of ammonia and sulphate of copper, there shall be recorded in a book kept for that purpose the name of the article, the quantity delivered, the purpose for which it is to be used, the date of delivery, the name and address of the person for whom it is procured, and the name of the individual personally dispensing the same; and said book shall be preserved by the owner thereof for at least three years after the date of

the last entry therein. The foregoing provisions shall not apply to articles dispensed upon the order of persons believed by the dispenser to be recognized and reputable practitioners of medicine, dentistry, or veterinary surgery. When a physician writes upon his prescription a request that it be marked or labeled "Poison" the pharmacist shall, in the case of liquids, place the same in a colored glass, roughened bottle, of the kind commonly known in trade as a "poison bottle", and, in the case of dry substances, he shall place a poison label upon the container. The record of sale and delivery above mentioned shall not be required of manufacturers and wholesalers who shall sell any of the foregoing substances at wholesale to licensed pharmacists, but the box, bottle, or other package containing such substance, when sold at wholesale, shall be properly labeled with the name of the substance, the word "poison", and the name and address of the manufacturer or wholesaler. It shall not be necessary, in sales either at wholesale or at retail, to place a poison label upon, nor to record the delivery of, the sulphide of antimony, or the oxide or carbonate of zinc, or of colors ground in oil and intended for use as paints, or calomel; nor in the case of preparations containing any of the substances named in this section, when a single box, bottle, or other package, or when the bulk of one-half fluid ounce or the weight of one-half avoirdupois ounce does not contain more than an adult medicinal dose of such substance; nor in the case of liniments or ointments sold in good faith as such, when plainly labeled "For external use only"; nor, in the case of preparations put up and sold in the form of pills, tablets, or lozenges, containing any of the substances enumerated in this section and intended for internal use, when the dose recommended does not contain more than one-fourth of an adult medicinal dose of such substance.

For the purpose of this and of every other section of this chapter no box, bottle, or other package shall be regarded as having been labeled "Poison" unless the word "Poison" appears conspicuously thereon, printed in plain, uncondensed gothic letters in red ink.

(Mar. 3, 1915, ch. 74, § 7, 38 Stat. 820.)

§ 210. Pharmacist; unauthorized use of title

It shall be unlawful for any person whose permanent allegiance is due to the United States, not legally licensed as a pharmacist, to take, use, or exhibit the title of pharmacist, or licensed or registered pharmacist, or the title of druggist or apothecary, or any other title or description of like import.

(Mar. 3, 1915, ch. 74, § 10, 38 Stat. 821.)

§ 211. Preservation of originals of prescriptions compounded and copies thereof; inspection of prescriptions by consular officers; marking containers of drugs

Every person, firm, or corporation whose permanent allegiance is due to the United States owning, partly owning, or managing a drug store or pharmacy shall keep in his place of business a suitable book or file, in which shall be preserved for a period of not less than three years the original of every prescription compounded or dispensed at such store or pharmacy, or a copy of such prescription, except when the preservation of the original is required by section 207 or 208 of this title. Upon request the owner, part owner, or manager of such store shall furnish to the prescribing physician, or to the person for whom such prescription was compounded or dispensed, a true and correct copy thereof. Any prescription required by section 207 or 208 of this title, and any prescription for, or register of sales of, substances mentioned in such sections shall at all times be open to inspection by duly authorized consular officers in the consular districts of the United States in China. No person, firm, or corporation whose permanent allegiance is due to the United States shall, in a consular district, compound or dispense any drug or drugs or deliver the same to any other person without marking on the container thereof the name of the drug or drugs contained therein and directions for using the same.

(Mar. 3, 1915, ch. 74, § 9, 38 Stat. 821.)

§ 212. Offenses; punishment; duty to enforce provisions

Any person, firm, or corporation, whose permanent allegiance is due to the United States, violating any of the provisions of this chapter shall be deemed guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not less than $50 and not more than $100 or by imprisonment for not less than one month and not more than sixty days, or by both such fine and imprisonment, in the discretion of the court, and if the offense be continuing in its character, each week or part of a week during which it continues shall constitute a separate and distinct offense. And it shall be the duty of the consular and judicial officers of the United States in China to enforce the provisions of this chapter.

(Mar. 3, 1915, ch. 74, § 11, 38 Stat. 821.)

§ 213. Fraudulent representations to evade or defeat restrictions

No person, firm, or corporation whose permanent allegiance is due to the United States seeking to procure in the consular districts of the United States in China any substance the sale of which is regulated by the provisions of this chapter shall make any fraudulent representations so as to evade or defeat the restrictions herein imposed.

(Mar. 3, 1915, ch. 74, § 8, 38 Stat. 821.)

§ 214. Previous laws unaffected

Nothing in this chapter shall be construed as modifying or revoking any of the provisions of sections 191 to 193 of this title.

(Mar. 3, 1915, ch. 74, § 13, 38 Stat. 822.)

References in Text

Sections 191 to 193 of this title, referred to in text, were repealed by Pub. L. 91-513, title III, § 1101(a)(1), Oct. 27, 1970, 84 Stat. 1291. See, now section 801 et seq. of this title.

§ 215. "Consul" defined

The word "consul" as used in this chapter shall mean the consular officer in charge of the district concerned.

(Mar. 3, 1915, ch. 74, § 12, 38 Stat. 822.)

CHAPTER 8—NARCOTIC FARMS

§§ 221 to 237. Repealed. July 1, 1944, ch. 373, title XIII, § 1313, 58 Stat. 714

Section 221, act Jan. 19, 1929, ch. 82, § 1, 45 Stat. 1085, which defined "habit forming narcotic drug, narcotic", and "addict", is now covered by section 201 of Title 42, The Public Health and Welfare.

Section 222, act Jan. 19, 1929, ch. 82, § 2, 45 Stat. 1085, which provided for narcotic farms, is now covered by section 257 of Title 42.

Section 222a, act June 23, 1935, ch. 725, § 1, 49 Stat. 1840, provided name for the narcotic farm at Lexington, Ky.

Section 222b, act Mar. 28, 1938, ch. 55, § 1, 52 Stat. 134, provided name for narcotic farm at Fort worth, Texas.

Section 223, act Jan. 19, 1929, ch. 82, § 3, 45 Stat. 1085; 1939 Reorg. Plan No. I, § 205(b), eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1425, provided for an annual estimate of expenses of maintenance of narcotic farms.

Section 224, act Jan. 19, 1929, ch. 82, § 4, 45 Stat. 1086, provided for construction of buildings for two of the narcotic farms.

Section 225, act Jan. 19, 1929, ch. 82, § 5, 45 Stat. 1086; June 14, 1930, ch. 488, § 4(a), 46 Stat. 586; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, provided for the control and management of narcotic farms.

Section 226, act Jan. 19, 1929, ch. 82, § 6, 45 Stat. 1086; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, which provided for the care and treatment of addicts, is now covered by section 257 of Title 42.

Section 227, act Jan. 19, 1929, ch. 82, § 7, 45 Stat. 1086, which provided for the transfer to and from farms of addicts who are prisoners, is now covered by section 259 of Title 42.

Section 228, act Jan. 19, 1929, ch. 82, § 8, 45 Stat. 1087, which provided that it was the duty of prosecuting officers to report convicted persons believed to be addicts, is now covered by section 259 of Title 42.

Section 229, act Jan. 19, 1929, ch. 82, § 9, 45 Stat. 1087; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, which provided for the employment of addicts, is now covered by section 258 of Title 42.

Section 230, act Jan. 19, 1929, ch. 82, § 10, 45 Stat. 1087, which provided for the parole of inmates, is now covered by section 259 of Title 42.

Section 231, act Jan. 19, 1929, ch. 82, § 11, 45 Stat. 1087; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, which provided for the discharge of addicts, is now covered by section 259 of Title 42.

Section 232, act Jan. 19, 1929, ch. 82, § 12, 45 Stat. 1088; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, which provided for the admission of voluntary patients, is now covered by section 260 of Title 42.

Section 233, act Jan. 19, 1929, ch. 82, § 13, 45 Stat. 1088; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, which provided for the furnishing of gratuities and transportation to discharged convicts, is now covered by section 259 of Title 42.

Section 234, act. Jan. 19, 1929, ch. 82, § 14, 45 Stat. 1089; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, which provided penalties for the introduction of narcotic drugs into a narcotic farm, is now covered by section 261 of Title 42.

Section 235, act Jan. 19, 1929, ch. 82, § 15, 45 Stat. 1089, which provided penalties for the escape of inmates, is now covered by section 261 of Title 42.

Section 236, act Jan. 19, 1929, ch. 82, § 16, 45 Stat. 1089, which provided penalties for the procuring of escape by inmates, is now covered by section 261 of Title 42.

Section 237, act Jan. 19, 1929, ch. 82, § 17, 45 Stat. 1089, provided for the deportation of alien inmates who are entitled to a discharge from narcotic farms.

RENUMBERING OF REPEALING ACT

Section 611 of act July 1, 1944, which repealed this section, was renumbered 711 by act Aug. 13, 1946, ch. 958, § 5, 60 Stat. 1049, 713 by act Feb. 28, 1948, ch. 83, § 9(b), 62 Stat. 47, 813 by act July 30, 1956, ch. 779, § 3(b), 70 Stat. 720, 913 by Pub. L. 88-581, § 4(b), Sept. 4, 1964, 78 Stat. 919, 1013 by Pub. L. 89-239, § 3(b), Oct. 6, 1965, 79 Stat. 931, 1113 by Pub. L. 91-572, § 6(b), Dec. 24, 1970, 84 Stat. 1506, 1213 by Pub. L. 92-294, § 3(b), May 16, 1972, 86 Stat. 137, 1313 by Pub. L. 93-154, § 2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93-222, § 7(b), Dec. 29, 1973, 87 Stat. 936.

CHAPTER 9—FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in sections 453, 457, 466, 467, 467f, 601, 607, 620, 679, 811, 829, 902, 1033, 1049, 1052 of this title; title 7 section 1431c; title 15 sections 70j, 1261, 1263, 1459, 1460, 2079; title 18 section 42; title 26 sections 170, 4817; title 42 sections 262, 3512.

SUBCHAPTER I—SHORT TITLE

§ 301. Short title

This chapter may be cited as the Federal Food, Drug, and Cosmetic Act.

(June 25, 1938, ch. 675, § 1, 52 Stat. 1040.)

EFFECTIVE DATE; POSTPONEMENT IN CERTAIN CASES

Act June 23, 1939, ch. 242, §§ 1, 2, 53 Stat. 853, 854, provided as follows:

"[Sec. 1] (a) The effective date of the following provisions of the Federal Food, Drug, and Cosmetic Act is hereby postponed until January 1, 1940: Sections 402(c) [342(c) of this title]; 403(e)(1) [343(e)(1) of this title]; 403(g), (h), (i), (j), and (k) [343(g) to (k) of this title]; 501(a), (4) [351(a)(4) of this title]; 502(b), (d), (e), (f), (g), and (h) [352(b), (d) to (h) of this title]; 601(e) [361(e) of this title]; and 602(b) [362(b) of this title].

"(b) The Secretary of Agriculture shall promulgate regulations further postponing to July 1, 1940 the effective date of the provisions of sections 403(e)(1) [343(e)(1) of this title]; 403(g), (h), (i), (j), and (k) [343(g) to (k)]; 502(b), (d), (e), (f), (g), and (h) [352(b), (d) to (h) of this title]; and 602(b) [362(b) of this title] of such Act with respect to lithographed labeling which was manufactured prior to February 1, 1939, and to containers bearing labeling which, prior to February 1, 1939, was lithographed, etched, stamped, pressed, printed, fused or blown on or in such containers, where compliance with such provisions would be unduly burdensome by reason of causing the loss of valuable stocks of such labeling or containers, and where such postponement would not prevent the public interest being adequately served: Provided, That in no case shall such regulations apply to labeling which would not have complied with the requirements of the Food and Drugs Act of June 30, 1906, as amended.

"Sec. 2. (a) The provisions of section 8 [section 10 of this title], paragraph fifth, under the heading 'In the case of food:', of the Food and Drugs Act of June 30, 1906, as amended, and regulations promulgated thereunder, and all other provisions of such Act to the extent that they may relate to the enforcement of such section 8 [section 10 of this title] and of such regulations, shall remain in force until January 1, 1940.

"(b) The provisions of such Act of June 30, 1906, as amended, [sections 1 to 5, 7 to 15, and 372a of this title] to the extent that they impose, or authorize the imposition of, any requirement imposed by section 403(k) of the Federal Food, Drug, and Cosmetic Act [section 343(k) of this title], shall remain in force until January 1, 1940.

"(c) Notwithstanding the provisions of section 1 of this Act, such section shall not apply—

"(1) to the provisions of section 502(d) and (e) of the Federal Food, Drug, and Cosmetic Act [352(d), (e) of this title], insofar as such provisions relate to any substance named in section 8 [section 10 of this title], paragraph second, under the heading 'In the case of drugs:', of the Food and Drugs Act of June 30, 1906, as amended, or a derivative of any such substance; or

"(2) to the provisions of section 502(b), (d), (e), (f), (g), and (h) of the Federal Food, Drug, and Cosmetic Act [352(b), (d) to (h) of this title], insofar as such provisions relate to drugs to which section 505 [355 of this title] of such Act applies."

EFFECTIVE DATE

Section 902(a) of act June 25, 1938, provided that: "This Act [enacting this chapter and repealing sections 1 to 5 and 7 to 15 of this title], shall take effect twelve months after the date of its enactment [June 25, 1938]. The Federal Food and Drugs Act of June 30, 1906, as amended (U.S.C., 1934 ed., title 21, secs. 1-15), shall remain in force until such effective date, and, except as otherwise provided in this subsection, is hereby repealed effective upon such date: *Provided*, That the provisions of section 701 [section 371 of this title] shall become effective on the enactment of this Act, and thereafter the Secretary is authorized hereby to (1) conduct hearings and to promulgate regulations which shall become effective on or after the effective date of this Act as the Secretary shall direct, and (2) designate prior to the effective date of this Act food having common or usual names and exempt such food from the requirements of clause (2) of section 403(i)

[section 343(i) of this title] for a reasonable time to permit the formulation, promulgation, and effective application of definitions and standards of identity therefor as provided by section 401 [section 341 of this title]: *Provided further,* That sections 502(j), 505, and 601(a) [sections 352(j), 355, 361(a), respectively of this title], and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act, except that in the case of a cosmetic to which the proviso of section 601(a) [section 361(a) of this title], relates, such cosmetic shall not, prior to the ninetieth day after such date of enactment, be deemed adulterated by reason of the failure of its label to bear the legend prescribed in such proviso: *Provided further,* That the Act of March 4, 1923 (U.S.C., 1934 ed., title 21, sec. 6 [now section 321(a) of this title]; 42 Stat. 1500, ch. 268), defining butter and providing a standard therefor; the Act of July 24, 1919 (U.S.C., 1934 ed., title 21, sec. 10 [now section 321(b) of this title]; 41 Stat. 271, ch. 261, defining wrapped meats as in package form; and the amendment to the Food and Drugs Act, section 10A, approved August 27, 1935 (U.S.C. 1934 ed., Sup. III, title 21, sec. 14a [now section 372a of this title]) shall remain in force and effect and be applicable to the provisions of this Act."

HAZARDOUS SUBSTANCES

Federal Hazardous Substances Act as not modifying this chapter, see Pub. L. 86-613, § 18, July 12, 1960, 74 Stat. 380, set out as a note under section 1261 of Title 15, Commerce and Trade.

SHORT TITLE OF 1976 AMENDMENT

Pub. L. 94-295, § 1(a), May 28, 1976, 90 Stat. 539, provided that: "This Act [enacting sections 360c to 360k, 379, and 379a of this title and section 3512 of Title 42, The Public Health and Welfare, and amending sections 321, 331, 334, 351, 352, 358, 360, 374, 376, and 381 of this title and section 55 of Title 15, Commerce and Trade] may be cited as the 'Medical Device Amendments of 1976'."

SHORT TITLE OF 1972 AMENDMENT

Section 1 of Pub. L. 92-387 provided that: "This Act [amending sections 331, 335, and 360 of this title and enacting provisions set out as notes under section 360 of this title] may be cited as the 'Drug Listing Act of 1972'."

SHORT TITLE OF 1968 AMENDMENT

Section 1 of Pub. L. 90-399 provided: "That this Act [which enacted section 360b of this title, amended sections 321, 331, 342, 351, 352, 357, 381, and 392 of this title, and enacted provisions set out as a note under section 360b of this title] may be cited as the 'Animal Drug Amendments of 1968'."

SHORT TITLE OF 1965 AMENDMENT

Section 1 of Pub. L. 89-74 provided: "That this Act [which amended sections 321, 331, 333, 334, 360, and 372 of this title and section 1114 of Title 18, Crimes and Criminal Procedure, and enacted provisions set out as notes under sections 321 and 352 of this title] may be cited as the 'Drug Abuse Control Amendments of 1965'."

SHORT TITLE OF 1960 AMENDMENT

Section 1 of Pub. L. 86-618 provided that Pub. L. 86-618, which amended sections 321, 331, 333, 342, 346, 351, 352, 361, 362, 371, and 376 of this title, repealed section 354 and 364 of this title, and enacted notes set out under this section, may be cited as the "Color Additive Amendments of 1960."

SHORT TITLE OF 1958 AMENDMENT

Section 1 of Pub. L. 85-929 provided: "That this Act [amending sections 321, 331, 342, 346, 348 of this title and section 210 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under sections 321, 342, and 451 of this title] may be cited as the 'Food Additives Amendment of 1958'."

ACT REFERRED TO IN D.C. CODE

This act is referred to in section 22-3422 of the District of Columbia Code.

SUBCHAPTER II—DEFINITIONS

§ 321. Definitions; generally

For the purposes of this chapter—

(a)(1) The term "State", except as used in the last sentence of section 372(a) of this title, means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the Department of Health, Education, and Welfare.

(d) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formularly, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories.

(2) The term "counterfeit drugs" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(*l*) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

(*o*) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q) The term "pesticide chemical" means any substance which, alone, in chemical combination or in formulation with one or more other substances, is "a pesticide" within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq] as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case as a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C.

451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C. 601 et seq.]; or

(5) a new animal drug.

(t)(1) The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term "safe" as used in paragraph (s) of this section and in sections 348, 360b, and 376 of this title, has reference to the health of man or animal.

(v) Repealed. Pub. L. 91-513, title II, § 701(a), Oct. 27, 1970, 84 Stat. 1281.

(w) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed,—

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions; or

(3) which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, except when there is in effect a published order of the Secretary declaring such drug not to be a new animal drug on the grounds that (A) the requirement of certification of batches of such drug, as provided for in section 360b(n) of this title, is not necessary to insure that the objectives specified in paragraph (3) thereof are achieved and (B) that neither subparagraph (1) nor (2) of this paragraph (w) applies to such drug.

(x) The term "animal feed", as used in paragraph (w) of this section, in section 360b of this title, and in provisions of this chapter referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(y) The term "informal hearing" means a hearing which is not subject to section 554, 556, or 557 of title 5 and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department of Health, Education, and Welfare who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(June 25, 1938, ch. 675, § 201, 52 Stat. 1041; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 78 Stat. 631; July 22, 1954, ch. 559, § 1, 68 Stat. 511; Sept. 6, 1958, Pub. L. 85-929, § 2, 72 Stat. 1784; July 12, 1960, Pub. L. 86-618, title I, § 101, 74 Stat. 397; Oct. 10, 1962, Pub. L. 87-781, title I, § 102(a),

title III, § 307(a), 76 Stat. 781, 796; July 15, 1965, Pub. L. 89-74, §§ 3(a), 9(b), 79 Stat. 227, 234; July 13, 1968, Pub. L. 90-399, § 102, 82 Stat. 351; Oct. 24, 1968, Pub. L. 90-639, §§ 1, 4(a), 82 Stat. 1361, 1362; Oct. 27, 1970, Pub. L. 91-513, title II, § 701(a), (g), 84 Stat. 1281, 1282; Oct. 21, 1972, Pub. L. 92-516, § 3(3), 86 Stat. 998; Apr. 22, 1976, Pub. L. 94-278, title V, § 502(a)(2)(A), 90 Stat. 411; May 28, 1976, Pub. L. 94-295, § 3(a)(1)(A), (2), 90 Stat. 575.)

REFERENCES IN TEXT

The Food and Drugs Act of June 30, 1906, as amended, referred to in subsecs. (p)(1) and (w)(1), is act June 30, 1906, ch. 3915, 34 Stat. 768, as amended, which was classified to subchapter I (§ 1 et seq.) of chapter 1 of this title, was repealed (except for section 14a which was transferred to section 372a of this title) by act June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059, and is now covered by this chapter.

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsec. (q), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92-516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (§ 136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables volume.

The Poultry Products Inspection Act, referred to in subsec. (s)(4), is Pub. L. 85-172, Aug. 28, 1957, 71 Stat. 441, as amended, which is classified generally to chapter 10 (§ 451 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 451 of this title and Tables volume.

The Meat Inspection Act, approved March 4, 1907, as amended and extended, referred to in subsec. (s)(4), is act Mar. 4, 1907, ch. 2907, titles I to IV, as added Dec. 15, 1967, Pub. L. 90-201, 81 Stat. 584, which are classified generally to subchapters I to IV (§ 601 et seq.) of chapter 12 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables volume.

AMENDMENTS

1976—Subsec. (h). Pub. L. 94-295, § 3(a)(1)(A), expanded the definition of "device" to include implements, machines, implants, in vitro reagents, and other similar or related articles, added recognition in the National Formulary or the United States Pharmacopeia, or any supplement to the Formulary or Pharmacopeia, to the enumeration of conditions under which a device may qualify for inclusion under this chapter, and added requirements that a device be one which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

Subsec. (n). Pub. L. 94-278 inserted "or advertising" after "labeling" wherever appearing.

Subsec. (y). Pub. L. 94-295, § 3(a)(2), added subsec. (y).

1972—Subsec. (q). Pub. L. 92-516 substituted reference to pesticide for reference to economic poison.

1970—Subsec. (a)(2). Pub. L. 91-513, § 701(g), struck out reference to sections 321, 331(l), 331(p), 331(q), 332, 333, 334, 337, 360, 360a, 372, 373, 374, and 375 of this title as they apply to depressant or stimulant drugs.

Subsec. (v). Pub. L. 91-513, § 701(a), struck out subsec. (v) which defined "depressant or stimulant drug".

1968—Subsec. (a)(2). Pub. L. 90-639, § 4(a), added material extending provisions covering depressant and stimulant drugs, the containers thereof, and equipment used in manufacturing, compounding, or processing such drugs, to the Canal Zone.

Subsec. (p). Pub. L. 90-399, § 102(a), (b), inserted "(except a new animal drug or an animal feed bearing or containing a new animal drug)" following "Any drug" in subpars. (1) and (2), respectively.

Subsec. (s). Pub. L. 90-399, § 102(c), added subpar. (5).

Subsec. (u). Pub. L. 90-399, § 102(d), inserted a reference to section 360b of this title.

Subsec. (v)(3). Pub. L. 90-639, § 1, added specific reference to lysergic acid diethylamide.

Subsecs. (w), (x). Pub. L. 90-399, § 102(e), added subsecs. (w) and (x).

1965—Subsec. (g). Pub. L. 89-74, § 9(b), designated existing provisions as subpar. (1), redesignated clauses (1) to (4) thereof as (A) to (D), substituted therein "(A), (B), or (C)" for "(1), (2), or (3)" and added subpar. (2).

Subsec. (v). Pub. L. 89-74, § 3(a), added subsec. (v).

1962—Subsec. (a). Pub. L. 87-781, § 307(a), designated existing provisions as clause (2), inserted "Commonwealth of Puerto Rico and the" therein, and added clause (1).

Subsec. (p)(1). Pub. L. 87-781, § 102(a)(1), inserted "and effectiveness" following "to evaluate the safety", and "and effective" following "as safe".

Subsec. (p)(2). Pub. L. 87-781, § 102(a)(2), inserted "and effectiveness" following "safety".

1960—Subsec. (s). Pub. L. 86-618, § 101(a), excluded color additives from the definition of the term "food additive".

Subsec. (t). Pub. L. 86-618, § 101(c), added subsec. (t). Former subsec. (t) redesignated (u).

Subsec. (u). Pub. L. 86-618, § 101(b), redesignated former subsec. (t) as (u) and included therein a reference to section 376 of this title.

1958—Subsecs. (s), (t). Pub. L. 85-929 added subsecs. (s) and (t).

1954—Subsecs. (q), (r). Act July 22, 1954, added subsecs. (q) and (r).

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94-278 effective 180 days after Apr. 22, 1976, see section 502(c) of Pub. L. 94-278, set out as an Effective Date of 1976 Amendment note under section 334 of this title.

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92-516 effective at the close of Oct. 21, 1972, except if regulations are necessary for the implementation of any provision that becomes effective on Oct. 21, 1972, and continuation in effect of subchapter I of chapter 6 of Title 7, and regulations thereunder, relating to the control of economic poisons, as in existence prior to Oct. 21, 1972, until superseded by provisions of Pub. L. 92-516, and regulations thereunder, see section 4 of Pub. L. 92-516, set out as an Effective Date note under section 136 of Title 7, Agriculture.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91-513 effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91-513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENTS; TRANSITIONAL PROVISIONS

Section 6 of Pub. L. 90-639 provided that: "The amendments made by this Act [amending sections 321, 331, 333, 334, and 360a of this title and section 289a note of Title 42, The Public Health and Welfare] shall apply only with respect to violations of the Federal Food, Drug, and Cosmetic Act [this chapter] committed after the date of the enactment of this Act [Oct. 24, 1968]."

Enactment of subsecs. (s)(5), (w), and (x), and amendment of subsecs. (p)(1), (2) and (u) of this section by Pub. L. 90-399 effective on first day of thirteenth calendar month after July 13, 1968, except that in the case of a drug (other than one subject to section 360b(n) of this title) intended for use in animals other

than man which, on Oct. 9, 1962, was commercially used or sold in the United States, was not a new drug as defined in subsec. (p) of this section then in force, and was not covered by an effective application under section 355 of this title, the words "effectiveness" and "effective" contained in subsec. (w) of this section not applicable to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day, see section 108(a), (b)(3) of Pub. L. 90–399, set out as an Effective Date note under section 360b of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Section 11 of Pub. L. 89–74 provided that: "The foregoing provisions of this Act [see Short Title of 1965 Amendment note below] shall take effect on the first day of the seventh calendar month [Feb. 1, 1966] following the month in which this Act is enacted [July 15, 1965]; except that (1) the Secretary shall permit persons, owning or operating any establishment engaged in manufacturing, preparing, propagating, compounding, processing, wholesaling, jobbing, or distributing any depressant or stimulant drug, as referred to in the amendments made by section 4 of this Act to section 510 of the Federal Food, Drug, and Cosmetic Act [section 360 of this title], to register their name, places of business, and establishments, and other information prescribed by such amendments, with the Secretary prior to such effective date, and (2) sections 201(v) and 511(g) of the Federal Food, Drug, and Cosmetic Act, as added by this act [subsec. (v) of this section and subsec. (g) of section 360a of this title], and the provisions of sections 8 [amending section 372 of this title and section 1114 of Title 18, Crimes and Criminal Procedure] and 10 [set out as a note under this section] shall take effect upon the date of enactment of this Act [July 15, 1965]."

EFFECTIVE DATE OF 1962 AMENDMENT

Section 107 of Pub. L. 87–781 provided that:

"(a) Except as otherwise provided in this section, the amendments made by the foregoing sections of this part A [amending sections 321, 331, 332, 348, 351 to 353, 355, 357, 376 of this title, and enacted provisions set out as a note under section 355 of this title] shall take effect on the date of enactment of this Act [Oct. 10, 1962].

"(b) The amendments made by sections 101, 103, 105, and 106 of this part A [to sections 331, 332, 351, 352, 355, and 357 of this title] shall, with respect to any drug, take effect on the first day of the seventh calendar month following the month in which this Act is enacted [Oct. 1962].

"(c)(1) As used in this subsection, the term 'enactment date' means the date of enactment of this Act; and the term 'basic Act' means the Federal Food, Drug, and Cosmetic Act [this chapter].

"(2) An application filed pursuant to section 505(b) of the basic Act [section 355(b) of this title] which was 'effective' within the meaning of that Act on the day immediately preceding the enactment date shall be deemed as of the enactment date, to be an application 'approved' by the Secretary within the meaning of the basic Act as amended by this Act.

"(3) In the case of any drug with respect to which an application filed under section 505(b) of the basic Act is deemed to be an approved application on the enactment date by virtue of paragraph (2) of this subsection—

"(A) the amendments made by this Act to section 201(p), and to subsections (b) and (d) of section 505, of the basic Act [subsec. (p) of this section, and subsecs. (b) and (d) of section 355 of this title], insofar as such amendments relate to the effectiveness of drugs, shall not, so long as approval of such application is not withdrawn or suspended pursuant to section 505(e) of that Act [section 355(e) of this title], apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application, but shall apply to any changed use, or conditions of use, prescribed, recommended, or suggested in its labeling, including such conditions of use as are the subject of an amendment or supplement to such application pending on, or filed after, the enactment date; and

"(B) clause (3) of the first sentence of section 505(e) of the basic Act, as amended by this Act [section 355(e) of this title], shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application (except with respect to such use, or conditions of use, as are the subject of an amendment or supplement to such approved application, which amendment or supplement has been approved after the enactment date under section 505 of the basic Act as amended by this Act [section 355 of this title]) until whichever of the following first occurs: (i) the expiration of the two-year period beginning with the enactment date; (ii) the effective date of an order under section 505(e) of the basic Act [section 355(e) of this title], other than clause (3) of the first sentence of such section 505(e) [section 355(e) of this title], withdrawing or suspending the approval of such application.

"(4) In the case of any drug which, on the day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force [subsec. (p) of this section], and (C) was not covered by an effective application under section 505 of that Act [section 355 of this title], the amendments to section 201(p) [subsec. (p) of this section] made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day."

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–618 effective, subject to the provisions of section 203 of Pub. L. 86–618, on July 12, 1960, see section 202 of Pub. L. 86–618, set out as an Effective Date of 1960 Amendment note under section 376 of this title.

EFFECTIVE DATE OF 1958 AMENDMENT

Subsecs. (s) and (t) effective Sept. 6, 1958, see section 6(a) of Pub. L. 85–929, set out as an Effective Date of 1958 Amendment note under section 342 of this title.

EFFECTIVE DATE OF 1954 AMENDMENT

Effective date of subsecs. (q) and (r), see section 5 of act July 22, 1954, set out as an Effective Date of 1954 Amendment note under section 342 of this title.

SAVINGS PROVISIONS

Section 702 of Pub. L. 91–513, as amended by Pub. L. 93–481, § 2, Oct. 26, 1974, 88 Stat. 1455, provided that:

"(a) Prosecutions for any violation of law occurring prior to the effective date [see Effective Date of 1970 Amendment note above] of section 701 [repealing section 360a of this title, and amending sections 321, 331, 333, 334, 360, 372, and 381 of this title, sections 1114 and 1952 of Title 18, Crimes and Criminal Procedure, and section 242 of Title 42, The Public Health and Welfare] shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

"(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of section 701 shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

"(c) All administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on the date of enactment of this Act [Oct. 27, 1970] shall be continued and brought to final determination in accord with laws and regulations in effect prior to such date of enactment. Where a drug is finally determined under such proceedings to be a depressant or stimulant drug,

as defined in section 201(v) of the Federal Food, Drug, and Cosmetic Act [subsec. (v) of this section], such drug shall automatically be controlled under this title [subchapter I of chapter 13 of this title] by the Attorney General without further proceedings and listed in the appropriate schedule after he has obtained the recommendation of the Secretary. Any drug with respect to which such a final determination has been made prior to the date of enactment of this Act which is not listed in section 202 [section 812 of this title] within schedules I through V shall automatically be controlled under this title [subchapter I of chapter 13 of this title] by the Attorney General without further proceedings, and be listed in the appropriate schedule, after he has obtained the recommendations of the Secretary.

"(d) Notwithstanding subsection (a) of this section or section 1103 [of Pub. L. 91-513, set out as a note under sections 171 to 174 of this title], section 4202 of title 18, United States Code, shall apply to any individual convicted under any of the laws repealed by this title or title III [subchapter I or subchapter II of chapter 13 of this title] without regard to the terms of any sentence imposed on such individual under such law."

Transfer of Functions

Functions of the Secretary of Health, Education, and Welfare under the Drug Abuse Control Amendments of 1965 (see Short Title of 1965 Amendment note above) transferred to the Attorney General except the function of regulating the counterfeiting of those drugs which are not "depressant or stimulant" drugs, see section 2 of Reorg. Plan No. 1 of 1968, set out in the Appendix to Title 5, Government Organization and Employees.

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

Congressional Findings and Declaration of Policy

Section 2 of Pub. L. 89-74 provided that: "The Congress hereby finds and declares that there is a widespread illicit traffic in depressant and stimulant drugs moving in or otherwise affecting interstate commerce; that the use of such drugs, when not under the supervision of a licensed practitioner, often endangers safety on the highways (without distinction of interstate and intrastate traffic thereon) and otherwise has become a threat to the public health and safety, making additional regulation of such drugs necessary regardless of the intrastate or interstate origin of such drugs; that in order to make regulation and protection of interstate commerce in such drugs effective, regulation of intrastate commerce is also necessary because, among other things, such drugs, when held for illicit sale, often do not bear labeling showing their place of origin and because in the form in which they are so held or in which they are consumed a determination of their place of origin is often extremely difficult or impossible; and that regulation of interstate commerce without the regulation of intrastate commerce in such drugs, as provided in this Act [see Short Title of 1965 Amendment note above], would discriminate against and adversely affect interstate commerce in such drugs."

Dissemination of Information Regarding the Dangers of Drug Abuse

Section 5 of Pub. L. 90-639 provided that: "It is the sense of the Congress that, because of the inadequate knowledge on the part of the people of the United States of the substantial adverse effects of misuse of depressant and stimulant drugs, and of other drugs liable to abuse, on the individual, his family, and the community, the highest priority should be given to Federal programs to disseminate information which may be used to educate the public, particularly young persons, regarding the dangers of drug abuse."

Effect of Drug Abuse Control Amendments of 1965 on State Laws

Section 10 of Pub. L. 89-74 provided that:

"(a) Nothing in this Act [adding section 360a of this title, amending sections 321, 331, 333, 334, 360, and 372 of this title and section 1114 of Title 18, Crimes and Criminal Procedure, and enacting provisions set out as notes under sections 321, 352, and 360a of this title] shall be construed as authorizing the manufacture, compounding, processing, possession, sale, delivery, or other disposal of any drug in any State in contravention of the laws of such State.

"(b) No provision of this Act nor any amendment made by it shall be construed as indicating an intent on the part of the Congress to occupy the field in which such provision or amendment operates to the exclusion of any State law on the same subject matter, unless there is a direct and positive conflict between such provision or amendment and such State law so that the two cannot be reconciled or consistently stand together.

"(c) No amendment made by this Act shall be construed to prevent the enforcement in the courts of any State of any statute of such State prescribing any criminal penalty for any act made criminal by any such amendment."

Effect of the Drug Amendments of 1962 on State Laws

Section 202 of Pub. L. 87-781 provided that: "Nothing in the amendments made by this Act [adding sections 358 to 360, amending sections 321, 331, 332, 348, 351 to 353, 355, 357, 372, 374, 376, and 381 of this title, and enacting provisions set out as notes under sections 321, 331, 332, 352, 355, 360, and 374 of this title] to the Federal Food, Drug, and Cosmetic Act [this chapter] shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law."

Cross References

Appropriations for purpose and administration of subsecs. (q) and (r) of this section, see section 346b of this title.

Section Referred to in Other Sections

This section is referred to in sections 346b, 350, 352, 376, 802, 825 of this title; title 7 section 136; title 15 sections 1454, 1456, 1471, 2052, 2602; title 18 sections 842, 922.

§ 321a. Butter defined

For the purposes of the Food and Drug Act of June 30, 1906 (Thirty-fourth Statutes at Large, page 768) "butter" shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.

(Mar. 4, 1923, ch. 268, 42 Stat. 1500.)

References in Text

The Food and Drug Act of June 30, 1906, referred to in text is act June 30, 1906, ch. 3915, 34 Stat. 768, as amended, which was classified to subchapter 1 (§ 1 et. seq.) of chapter 1 of this title, was repealed (except for section 14a which was transferred to section 372a of this title) by act June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059, and is now covered by this chapter.

CODIFICATION

Section, which is not a section of the Federal Food, Drug, and Cosmetic Act, which comprises this chapter, was formerly section 6 of this title. Act June 25, 1938, provided that the section should remain in force and effect and be applicable to the provisions of this chapter. See section 902(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title.

§ 321b. Package defined

The word "package" where it occurs the second and last time in the act entitled "An act to amend section 8 of an act entitled, 'An act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes,'" approved March 3, 1913, shall include and shall be construed to include wrapped meats inclosed in papers or other materials as prepared by the manufacturers thereof for sale.

(July 24, 1919, ch. 26, 41 Stat. 271.)

REFERENCES IN TEXT

An act approved March 3, 1913, referred to in text, is act Mar. 3, 1913, ch. 117, 37 Stat. 732, which amended section 10 of this title. For complete classification of this Act to the Code, see Tables volume.

"An act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes,", referred to in text, is act June 30, 1906, ch. 3915, 34 Stat. 768, which was classified to subchapter I (§ 1 et seq.) of chapter 1 of this title, was repealed (except for section 14a which was transferred to section 372a of this title) by act June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059, and is now covered by this chapter.

CODIFICATION

Section, which is not a section of the Federal Food, Drug, and Cosmetic Act, which comprises this chapter, was formerly the last sentence of paragraph third of section 10 of this title, and was made applicable to this chapter by section 902(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title.

§ 321c. Nonfat dry milk; milk

For the purposes of the Federal Food, Drug, and Cosmetic Act of June 26, 1938, (ch. 675, sec. 1, 52 Stat. 1040) [21 U.S.C. 301 et seq.] nonfat dry milk is the product resulting from the removal of fat and water from milk, and contains the lactose, milk proteins, and milk minerals in the same relative proportions as in the fresh milk from which made. It contains not over 5 per centum by weight of moisture. The fat content is not over 1½ per centum by weight unless otherwise indicated.

The term "milk", when used herein, means sweet milk of cows.

(Mar. 2, 1944, ch. 77, 58 Stat. 108; July 2, 1956, ch. 495, 70 Stat. 486.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act of June 26, 1938 (ch. 675, sec. 1, 52 Stat. 1040), referred to in text, probably means act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to this chapter (§ 301 et seq.). For complete classification to this Act to the Code, see Tables volume.

CODIFICATION

Section was not enacted as a part of the Federal Food, Drug, and Cosmetic Act, which comprises this chapter, but was made applicable thereto.

AMENDMENTS

1956—Act July 2, 1956, substituted "nonfat dry milk" for "nonfat dry milk solids or defatted milk solids".

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in section 378 of this title.

§ 331. Prohibited acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344 or 355 of this title.

(e) The refusal to permit access to or copying of any record as required by section 373 of this title; or the failure to establish or maintain any record, or make any report, required under section 355(i) or (j), 357(d) or (g), 360b(j), (*l*), or (m), 360e(f), or 360i of this title, or the refusal to permit access to or verification or copying of any such required record.

(f) The refusal to permit entry or inspection as authorized by section 374 of this title.

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 333(c)(2) of this title which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 333(c)(3) of this title which guaranty or undertaking is false.

(i)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of sections 344, 356, 357, or 376 of this title.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of sections 344, 348, 355, 356, 357, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 374, 376, or 379 of this title concerning any method or process which as a trade secret is entitled to protection.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(*l*) The using, on the labeling of any drug or device or in any advertising relating to such drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under section 355, 360e, or 360j(g) of this title, as the case may be, or that such drug or device complies with the provisions of such section.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of subsections (b) or (c) of section 347 of this title.

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 374 of this title.

(*o*) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

(p) The failure to register in accordance with section 360 of this title, the failure to provide any information required by section 360(j) or 360(k) of this title, or the failure to provide a notice required by section 360(j)(2) of this title.

(q)(1) The failure or refusal to (A) comply with any requirement prescribed under section 360h or 360j(g) of this title, or (B) furnish any notification or other material or information required by or under section 360i or 360j(g) of this title.

(2) With respect to any device, the submission of any report that is required by or under this chapter that is false or misleading in any material respect.

(r) The movement of a device in violation of an order under section 334(g) of this title or the removal or alteration of any mark or label required by the order to identify the device as detained.

(June 25, 1938, ch. 675, § 301, 52 Stat. 1042; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; Dec. 22, 1941, ch. 613, § 1, 55 Stat. 851; July 6, 1945, ch. 281, § 1, 59 Stat. 463; Mar. 10, 1947, ch. 16, § 1, 61 Stat. 11; June 24, 1948, ch. 613, § 1, 62 Stat. 582; Mar. 16, 1950, ch. 61, § 3(b), 64 Stat. 20; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 7, 1953, ch. 350, § 2, 67 Stat. 477; Sept. 6, 1958, Pub. L. 85-929, § 5, 72 Stat. 1788; July 12, 1960, Pub. L. 86-618, title I, §§ 104, 105(a), 74 Stat. 403; Oct. 10, 1962, Pub. L. 87-781, title I, §§ 103(c), 104(e)(1), 106(c), 114(a), title III, § 304, 76 Stat. 784, 785, 788, 791, 795; July 15, 1965, Pub. L. 89-74, §§ 5, 9(c), 79 Stat. 232, 235; July 13, 1968, Pub. L. 90-399, § 103, 82 Stat. 352; Oct. 24, 1968, Pub. L. 90-639, § 2(b), 82 Stat. 1361; Oct. 27, 1970, Pub. L. 91-513, title II, § 701(a), 84 Stat. 1281; Aug. 16, 1972, Pub. L. 92-387, § 4(e), 86 Stat. 562; May 28, 1976, Pub. L. 94-295, §§ 3(b), 4(b)(1), 7(b), 90 Stat. 576, 580, 582.)

AMENDMENTS

1976—Subsec. (e). Pub. L. 94-295, § 3(b)(2), added references to sections 360e(f) and 360i of this title.

Subsec. (j). Pub. L. 94-295, § 3(b)(3), added references to sections 360, 360c, 360d, 360e, 360f, 360h, 360i, 360j, and 379 of this title.

Subsec. (*l*). Pub. L. 94-295, § 3(b)(4), substituted "drug or device" for "drug" wherever appearing and added references to sections 360e and 360j(g) of this title.

Subsec. (p). Pub. L. 94-295, § 4(b)(1), substituted "section 360(j) or 360(k) of this title," for "section 360(j) of this title,".

Subsec. (q). Pub. L. 94-295, § 3(b)(1), added subsec. (q).

Subsec. (r). Pub. L. 94-295, § 7(b), added subsec. (r).

1972—Subsec. (p). Pub. L. 92-387 added failure to provide information required by section 360(j) of this title, and failure to provide notice required by section 360(j)(2) of this title as prohibited acts.

1970—Subsec. (q). Pub. L. 91-513 struck out subsec. (q) which set out penalties for illegal manufacture, sale, disposition, possession and other traffic in stimulant and depressant drugs. See section 801 et seq. of this title.

1968—Subsec. (e). Pub. L. 90-399, § 103(1), inserted reference to section 360b(j), (*l*), and (m) of this title.

Subsec. (j). Pub. L. 90-399, § 103(2), inserted reference to section 360b of this title.

Subsec. (q). Pub. L. 90-639 divided clause (3), which had formerly referred simply to possession in violation of section 360a(c) of this title, into parts (A) and (B) which refer, respectively, to possession in violation of section 360a(c)(1) of this title and possession in violation of section 360a(c)(2) of this title.

1965—Subsec. (i). Pub. L. 89-74, § 9(c), designated existing provisions as subpar. (1) and added subpars. (2) and (3).

Subsec. (q). Pub. L. 89-74, § 5, added subsec. (q).

1962—Subsec. (e). Pub. L. 87-781, §§ 103(c), 106(c), prohibited the failure to establish or maintain any record, or make any report, required under sections 355(i) or (j) and 507(d) or (g) of this title, or the refusal to permit access to, or verification or copying of, any such required record.

Subsec. (*l*). Pub. L. 87-781, § 104(e)(1), inserted "approval of" preceding "an application", and substituted "in effect" for "effective".

Subsec. (o). Pub. L. 87-781, § 114(a), added subsec. (o).

Subsec. (p). Pub. L. 87-781, § 304, added subsec. (p).

1960—Subsec. (i). Pub. L. 86-618, § 105(a), eliminated references to sections 346(b) and 364 of this title and inserted a reference to section 376 of this title.

Subsec. (j). Pub. L. 86-618, § 104, inserted a reference to section 376 of this title.

1958—Subsec. (j). Pub. L. 85-929, inserted "348" following "344".

1953—Subsec. (n). Act Aug. 7, 1953, added subsec. (n).

1950—Subsec. (m). Act Mar. 16, 1950, added subsec. (m).

1948—Subsec. (k). Act June 24, 1948, inserted "(whether or not the first sale)" so as to make it clear that this subsection is not limited to the case where the act occurs while the article is held for the first sale after interstate shipment, and extended coverage of subsection to acts which result in adulteration.

1947—Subsec. (j). Act Mar. 10, 1947, inserted "356, 357" following "344, 355".

1945—Subsec. (i). Act July 6, 1945, inserted "357" following "356".

1941—Subsec. (i). Act Dec. 22, 1941, inserted reference to section 356.

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92-387 effective on the first day of the sixth month beginning after Aug. 16, 1972, see section 5 of Pub. L. 92-387, set out as an Effective Date of 1972 Amendment note under section 360 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91-513 effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91-513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENTS

Amendment of subsecs. (e) and (j) of this section by Pub. L. 90-399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90-399, set out as an Effective Date note under section 360b of this title.

Amendment by Pub. L. 90-639 applicable only with respect to violations of this chapter committed after Oct. 24, 1968, see section 6 of Pub. L. 90-639, set out as an Effective Date of 1968 Amendment note under section 321 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89-74 effective Feb. 1, 1966, see section 11 of Pub. L. 89-74, set out as an Effective Date of 1965 Amendment note under section 321 of this title.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment of subsec. (e) by Pub. L. 87-781 effective on the first day of the seventh calendar month following Oct. 1962, see section 107 of Pub. L. 87-781, set out as an Effective Date of 1962 Amendment note under section 321 of this title.

Section 114(b) of Pub. L. 87-781 provided that: "This section [adding subsec. (o) to this section] shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted [Oct. 1962]."

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective, subject to the provisions of section 203 of Pub. L. 86-618, on July 12, 1960, see section 202 of Pub. L. 86-618, set out as an Effective Date of 1960 Amendment note under section 376 of this title.

EFFECTIVE DATE OF 1958 AMENDMENT

Amendment of subsec. (j) effective Sept. 6, 1958, see section 6(a) of Pub. L. 85-929, set out as an Effective Date of 1958 Amendment note under section 342 of this title.

EFFECTIVE DATE OF 1950 AMENDMENT

Amendment by act Mar. 16, 1950, effective July 1, 1950, see section 7 of act Mar. 16, 1950, set out as an Effective Date note set out under section 347 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions notes set out under section 41 of this title.

SAVINGS PROVISIONS

Amendment by Pub. L. 91-513 not to affect or abate any prosecutions for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91-513, set out as a Savings Provisions note under section 321 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 332, 333, 347b, 360j of this title; title 15 section 1456.

§ 332. Injunction proceedings

(a) Jurisdiction of courts

The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 381 (relating to notice to opposite party) of title 28, as amended, to restrain violations of section 331 of this title, except paragraphs (h) to (j) of said section.

(b) Violation of injunction

In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 387 of title 28, as amended.

(June 25, 1938, ch. 675, § 302, 52 Stat. 1043; Oct. 10, 1962, Pub. L. 87-781, title I, § 103(d), title II, § 201(c), 76 Stat. 784, 793.)

REFERENCES IN TEXT

Section 381 of title 28, as amended, referred to in subsec. (a), was repealed by act June 25, 1948, ch. 646, § 39, 62 Stat. 992, eff. Sept. 1, 1948, and is now covered by rule 65 of Federal Rules of Civil Procedure, Title 28, Appendix, Judiciary and Judicial Procedure.

Section 387 of title 28, as amended, referred to in subsec. (b), was repealed by act June 25, 1948, ch. 645, § 21, 62 Stat. 862, and is now covered by section 402 of Title 18, Crimes and Criminal Procedure, and rule 42(b) of the Federal Rules of Criminal Procedure, Title 18, Appendix.

AMENDMENTS

1962—Subsec. (a). Pub. L. 87-781 eliminated references to subsecs. (e) and (f) of section 331 of this title.

EFFECTIVE DATE OF 1962 AMENDMENT

Section 203 of Pub. L. 87-781 provided that: "The amendments made by this title [amending section 374 of this title, eliminating "(f)" from subsec. (a) of this

section, and enacting provisions set out as notes under sections 321, 374 of this title] shall take effect on the date of enactment of this Act [Oct. 10, 1962]."

Amendment of subsec. (a) by Pub. L. 87-781, which eliminated "(e),", effective on the first day of the seventh calendar month following Oct. 1962, see section 107 of Pub. L. 87-781, set out as an Effective Date of 1962 Amendment note under section 321 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 334, 360j of this title; title 15 section 1456.

§ 333. Penalties

(a) Violation of section 331 of this title

Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(b) Second offenses; intent to defraud or mislead

Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

(c) Exceptions in certain cases of good faith, etc.

No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 331(a) or (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331(a) of this title, that such article is not adulterated or misbranded, within the meaning of this chapter designating this chapter or to the effect, in case of an alleged violation of section 331(d) of this title, that such article is not an article which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce; or (3) for having violated section 331(a) of this title, where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this chapter, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this chapter; or (4) for having violated section 331(b), (c) or (k) of this title by failure to comply with section 352(f) of this title in respect to an article received in interstate commerce to which neither section 353(a) nor 353(b)(1) of this title is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or (5) for having violated section 331(i)(2) of this title if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 331(i)(3) of this title if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

(d) Exceptions involving misbranded food

No person shall be subject to the penalties of subsection (a) of this section for a violation of section 331 of this title involving misbranded food if the violation exists solely because the food is misbranded under section 343(a)(2) of this title because of its advertising, and no person shall be subject to the penalties of subsection (b) of this section for such a violation unless the violation is committed with the intent to defraud or mislead.

(June 25, 1938, ch. 675, § 303, 52 Stat. 1043; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; Oct. 26, 1951, ch. 578, § 2, 65 Stat. 649; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; July 12, 1960, Pub. L. 86-618, title I, § 105(b), 74 Stat. 403; July 15, 1965, Pub. L. 89-74, §§ 7, 9(d), 79 Stat. 233, 235; Oct. 24, 1968, Pub. L. 90-639, § 3, 82 Stat. 1361; Oct. 27, 1970, Pub. L. 91-513, title II, § 701(b), 84 Stat. 1281; Apr. 22, 1976, Pub. L. 94-278, title V, § 502(a)(2)(B), 90 Stat. 411.)

AMENDMENTS

1976—Subsec. (d). Pub. L. 94-278 added subsec. (d).

1970—Subsec. (a). Pub. L. 91-513 struck out reference to subsec. (b) of this section and transferred to subsec. (b) provisions covering second offenses and offenses committed with intent to defraud or mislead.

Subsec. (b). Pub. L. 91-513 inserted provisions covering second offenses and offenses committed with intent to defraud or mislead formerly set out in subsec. (a) and struck out provisions covering violations involving depressant and stimulant drugs. See, now, section 801 et seq. of this title.

1968—Subsecs. (a), (b). Pub. L. 90-639 made a general revision in the penalties prescribed for offenses involving depressant or stimulant drugs, set a fine of not to exceed $10,000 or imprisonment of not more than 5 years for offenses involving the unlawful manufacturing of, sale, or disposal of, or possession with intent to sell, a depressant or stimulant drug or involving counterfeit depressant or stimulant drugs, stiffened the penalties for unlawful sales or other disposals by persons over 18 to persons under 21, and set new penalties for possession of a depressant or stimulant drug for purposes other than sale or other disposal.

1965—Subsec. (a). Pub. L. 89-74, § 7(a), added the proviso limiting the penalties for depressant or stimulant drug violations to two years imprisonment or $5,000 fine or both for first offense and to two years imprisonment or $15,000 fine or both for subsequent offenses.

Subsec. (b). Pub. L. 89-74, § 7(b), inserted the parenthetical exception provision.

Subsec. (c). Pub. L. 89-74, § 9(d), added cl. (5).

1960—Subsec. (c). Pub. L. 86-618 substituted in cl. (3), "a color additive" for "a coal-tar color", "the color additive" for "the coal-tar color" and "such color additive was" for "such color was".

1951—Subsec. (c)(4). Act Oct. 26, 1951, added subsec. (c)(4).

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment of section by Pub. L. 94-278 effective 180 days after Apr. 22, 1976, see section 502(c) of Pub. L. 94-278, set out as an Effective Date of 1976 Amendment note under section 334 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91-513 effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91-513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment of Pub. L. 90-639 applicable only with respect to violations of this chapter committed after Oct. 24, 1968, see section 6 of Pub. L. 90-639, set out as an Effective Date of 1968 Amendment note under section 321 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89-74 effective Feb. 1, 1966, see section 11 of Pub. L. 89-74, set out as an Effective Date of 1965 Amendment note under section 321 of this title.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective, subject to the provisions of section 203 of Pub. L. 86-618, on July 12, 1960, see section 202 of Pub. L. 86-618, set out as an Effective Date of 1960 Amendment note under section 376 of this title.

EFFECTIVE DATE OF 1951 AMENDMENT

Section 3 of act Oct. 26, 1951, provided that the amendment of this section should take effect six months after Oct. 26, 1951.

SAVINGS PROVISIONS

Amendment by Pub. L. 91-513 not to affect or abate any prosecutions for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91-513, set out as a Savings Provisions note under section 321 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

CROSS REFERENCES

Furnishing of guaranties, applicability to raw agricultural commodities, see section 346a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 346a, 360j, 845 of this title; title 15 section 1456.

§ 334. Seizure

(a) Grounds and jurisdiction

(1) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found: *Provided, however,* That no libel for condemnation shall be instituted under this chapter, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this chapter based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this chapter, or (B) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate wihtin a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found: (A) Any drug that is a counterfeit drug, (B) Any container of a counterfeit drug, (C) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs, and (D) Any adulterated or misbranded device.

(3)(A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any food which—

(i) is misbranded under section 343(a)(2) of this title because of its advertising, and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a food described in subparagraph (A) if—

(i)(I) the food's advertising which resulted in the food being misbranded under section 343(a)(2) of this title was disseminated in the establishment in which the food is being held for sale to the ultimate consumer,

(II) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

(III) all or part of the cost of such advertising was paid by such owner or operator; and

(ii) the owner or operator of such establishment used such advertising in the establishment to promote the sale of the food.

(b) Procedure; multiplicity of pending proceedings

The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) Availability of samples of seized goods prior to trial

The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) Disposition of goods after decree of condemnation; claims for remission or mitigation of forfeitures

(1) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold: *Provided,* That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter, under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the article was imported, and (B) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 381(d) of this title can and will be met: *Provided, however,* That the provisions of this sentence shall not apply where condemnation is based upon violation of section 342(a)(1), (2), or (6), section 351(a)(3), section 352(j), or section 361(a) or (d) of this title: *And provided further,* That where such exportation is made to the original foreign supplier, then clauses (1) and (2) of section 381(d) of this title and the foregoing proviso shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 381(d) of this title have been met. Any article condemned by reason of its being an article which may not, under section 344 or 355 of this title, be introduced into interstate commerce, shall be disposed of by destruction.

(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a) of this section.

(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a) of this section, the condemnation of any equipment or thing (other than a drug) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court (i) that he has not committed or caused to be committed any prohibited act referred to in such paragraph (2) and has no interest in any drug referred to therein, (ii) that he has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by him in good faith, and (iii) that he at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to counterfeit drugs.

(e) Costs

When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be

awarded against the person, if any, intervening as claimant of the article.

(f) Removal of case for trial

In the case of removal for trial of any case as provided by subsection (a) or (b) of this section—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

(g) Administrative restraint; detention orders

(1) If during an inspection conducted under section 374 of this title of a facility or a vehicle, a device which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under subsection (a) of this section or section 332 of this title, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device during the period of its detention for the purpose of identifying the device as detained. Any person who would be entitled to claim a device if it were seized under subsection (a) of this section may appeal to the Secretary a detention of such device under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

(2)(A) Except as authorized by subparagraph (B), a device subject to a detention order issued under paragraph (1) shall not be moved by any person from the place at which it is ordered detained until—

(i) released by the Secretary, or

(ii) the expiration of the detention period applicable to such order,

whichever occurs first.

(B) A device subject to a detention order under paragraph (1) may be moved—

(i) in accordance with regulations prescribed by the Secretary, and

(ii) if not in final form for shipment, at the discretion of the manufacturer of the device for the purpose of completing the work required to put it in such form.

(June 25, 1938, ch. 675, § 304, 52 Stat. 1044; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; June 24, 1948, ch. 613, § 2, 62 Stat. 582; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 7, 1953, ch. 350, § 3, 67 Stat. 477; Aug. 31, 1957, Pub. L. 85-250, 71 Stat. 567; July 15, 1965, Pub. L. 89-74, § 6, 79 Stat. 232; Oct. 24, 1968, Pub. L. 90-639, § 4(b), 82 Stat. 1362; Oct. 27, 1970, Pub. L. 91-513, title II, § 701(c), (d), 84 Stat. 1281, 1282; Apr. 22, 1976, Pub. L. 94-278, title V, § 502(a)(2)(C), 90 Stat. 411; May 28, 1976, Pub. L. 94-295, §§ 3(c), 7(a), 90 Stat. 576, 582.)

AMENDMENTS

1976—Subsec. (a)(1). Pub. L. 94-295, § 3(c)(1), struck out "device," following "Any article of food, drug,".

Subsec. (a)(2). Pub. L. 94-295, § 3(c)(2), (3), added cl. (D) covering adulterated or misbranded devices.

Subsec. (a)(3). Pub. L. 94-278 added subsec. (a)(3).

Subsec. (g). Pub. L. 94-295, § 7(a), added subsec. (g).

1970—Subsec. (a)(2). Pub. L. 91-513, § 701(c), struck out cls. (A) and (D) which dealt with depressant or stimulant drugs, struck out reference to depressant or stimulant drugs in cl. (C), and redesignated cls. (B), (C), and (E) as cls. (A), (B), and (C), respectively.

Subsec. (d)(3)(iii). Pub. L. 91-513, § 701(d), struck out reference to depressant or stimulant drugs.

1968—Subsec. (a). Pub. L. 90-639 inserted references to the United States courts of Territories.

1965—Subsec. (a). Pub. L. 89-74, § 6(a), designated existing provisions as par. (1), redesignated clauses (1) and (2) of the proviso thereto as (A) and (B) and added par. (2).

Subsec. (b). Pub. L. 89-74, § 6(b)(1), inserted in the first sentence "equipment, or other thing proceeded against" following "article".

Subsec. (d). Pub. L. 89-74, § 6(b)(2), designated existing provisions as par. (1) redesignated clauses (1) and (2) of the second sentence thereof as (A) and (B), and added pars. (2) and (3).

1957—Subsec. (d). Pub. L. 85-250 permitted, under certain circumstances, reexportation of articles condemned at places other than original port of entry.

1953—Subsec. (c). Act Aug. 7, 1953, provided that a true copy of the analysis in any case shall be furnished the owner.

1948—Subsec. (a). Act June 24, 1948, inserted "or while held for sale (whether or not the first sale) after shipment in interstate commerce" to make this subsection coextensive with section 331(k) of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Section 502(c) of Pub. L. 94-278 provided that: "The amendments made by subsection (a) [amending sections 321, 333, 334, and 343 of this title] shall take effect 180 days after the date of the enactment of this Act [Apr. 22, 1976]."

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91-513 effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91-513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90-639 applicable only with respect to violations of this chapter committed after Oct. 24, 1968, see section 6 of Pub. L. 90-639, set out as an Effective Date of 1968 Amendment note under section 321 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89-74 effective Feb. 1, 1966, see section 11 of Pub. L. 89-74, set out as an Effective Date of 1965 Amendment note under section 321 of this title.

SAVINGS PROVISIONS

Amendment by Pub. L. 91-513 not to affect or abate any prosecutions for any violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91-513, set out as a Savings Provisions note under section 321 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 360j, 372 of this title; title 15 section 1456.

§ 335. Hearing before report of criminal violation

Before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

(June 25, 1938, ch. 675, § 305, 52 Stat. 1045; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 15 section 1456.

§ 336. Report of minor violations

Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

(June 25, 1938, ch. 675, § 306, 52 Stat. 1045; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 15 section 1456.

§ 337. Proceedings in name of United States; provision as to subpoenas

All such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding.

(June 25, 1938, ch. 675, § 307, 52 Stat. 1046; Sept. 3, 1954, ch. 1263, § 37, 68 Stat. 1239.)

AMENDMENTS

1954—Act Sept. 3, 1954, eliminated reference to former section 654 of Title 28 which has been repealed.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 15 section 1456.

SUBCHAPTER IV—FOOD

§ 341. Definitions and standards for food

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

(June 25, 1938, ch. 675, § 401, 52 Stat. 1046; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Apr. 15, 1954, ch. 143, § 1, 68 Stat. 54; Aug. 1, 1956, ch. 861, § 1, 70 Stat. 919.)

AMENDMENTS

1956—Act Aug. 1, 1956, designated provisions constituting subsec. (a) as entire section and repealed subsec. (b), which provided the procedure for establishment of regulations and is now covered by section 371(e) of this title.

1954—Subsec. (a). Act Apr. 15, 1954, designated former section as subsec. (a).
Subsec. (b). Act Apr. 15, 1954, added subsec. (b).

SAVINGS PROVISIONS

Section 3 of act Aug. 1, 1956, provided that: "In any case in which, prior to the enactment of this Act [Aug. 1, 1956], a public hearing has been begun in accordance with section 401 of the Federal Food, Drug, and Cosmetic Act [341 of this title] upon a proposal to issue, amend, or repeal any regulation contemplated by such section, or has been begun in accordance with section 701(e) of such Act [section 371(e) of this title] upon a proposal to issue, amend, or repeal any regulation contemplated by section 403(j), 404(a), 406(a) or (b), 501(b), 502(d), 502(h), 504 or 604 of such Act [section 343(j), 344(a), 346(a) or (b), 351(b), 352(d), 352(h), 354, or 364 of this title], the provisions of such section 401 or 701(e), as the case may be, as in force immediately prior to the date of the enactment of this Act [Aug. 1, 1956], shall be applicable as though this Act [amending this section and section 371(e) of this title] had not been enacted."

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 343, 350, 371 of this title.

§ 342. Adulterated food

A food shall be deemed to be adulterated—

(a) Poisonous, insanitary, etc., ingredients

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 346 of this title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a(a) of this title, or (C) if it is, or if it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity, or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 360b of this title; (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

(b) Absence, substitution, or addition of constituents

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) Color additives

If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 376(a) of this title.

(d) Confectionery containing alcohol or nonnutritive substance

If it is confectionery, and—

(1) has partially or completely imbedded therein any nonnutritive object: *Provided*, That this clause shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts; or

(3) bears or contains any nonnutritive substance: *Provided*, That this clause shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this chapter: *And provided further*, That the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this clause, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

(e) Oleomargarine containing filthy, putrid, etc., matter

If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

(June 25, 1938, ch. 675, § 402, 52 Stat. 1046; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; Mar. 16, 1950, ch. 61, § 3(d), 64 Stat. 20; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; July 22, 1954, ch. 559, § 2, 68 Stat. 511; July 9, 1956, ch. 530, 70 Stat. 512; Sept. 6, 1958, Pub. L. 85-929, § 3(a), (b), 72 Stat. 1784; Mar. 17, 1959, Pub. L. 86-2, 73 Stat. 3; July 12, 1960, Pub. L. 86-618, title I, §§ 102(a)(1), (2), 105(c), 74 Stat. 397, 404; June 29, 1966, Pub. L. 89-477, 80 Stat. 231; July 13, 1968, Pub. L. 90-399, § 104, 82 Stat. 352.)

AMENDMENTS

1968—Subsec. (a)(2). Pub. L. 90-399 added item (iv) in cl. (A) and cl. (D), respectively.

1966—Subsec. (d). Pub. L. 89-477 permitted the imbedding of nonnutritive objects in confectionery foods if in the judgment of the Secretary of Health, Education, and Welfare, as provided by regulation, the imbedding of the object is of practical functional value to the confectionery product and would not render it injurious or hazardous to health, raised to one-half of 1 per centum by volume the upper limit for the allowable use of alcohol derived solely from the use of flavoring extracts, allowed the use of safe nonnutritive substances in and on confectionery foods by reason of their use for some practical and functional purpose in the manufacture, packaging, or storage of the confectionery foods if the use of the substances does not promote deception of the consumer or otherwise result in adulteration or misbranding, authorized the Secretary to issue regulations on the use of particular nonnutritive substances, and removed reference to nonnutritive masticatory substances added to chewing gum and harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, authorized coloring, and pectin.

1960—Subsec. (a). Pub. L. 86-618, § 102(a)(1), substituted "other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive" for "(except a pesticide chemical in or on a raw agricultural commodity and except a food additive)" in cl. (2)(A).

Subsec. (c). Pub. L. 86-618, § 102(a)(2), amended subsection (c) generally by substituting provisions deeming a food adulterated if it is, or it bears or contains, a color additive which is unsafe within the meaning of section 376 of this title for provisions which related to food that bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 346 of this title, and eliminated provisos which related to the use of color on oranges.

Subsec. (d). Pub. L. 86-618, § 105(c), substituted "authorized coloring" for "harmless coloring".

1959—Subsec. (c). Pub. L. 86-2 extended from March 1, 1959 to May 1, 1959, the period during which subsection is inapplicable to oranges which have been colored with F.D. & C. Red 32, and inserted proviso requiring Secretary to establish regulations prescribing the conditions under which Citrus Red No. 2 may be safely used in coloring certain mature oranges, and providing for separately listing and for certification of batches of such color.

1958—Subsec. (a). Pub. L. 85-929, among other changes, inserted clause (2)(C) relating to food additive unsafe within the meaning of section 348 of this title, and to pesticide chemical, and added clause (7), relating to radiated food.

1956—Subsec. (c). Act July 9, 1956, added second proviso relating to the coloring of oranges.

1954—Subsec. (a)(2). Act July 22, 1954, provided in the case of any raw agricultural commodity bearing or containing a pesticide chemical, that such commodity shall be deemed to be adulterated if such pesticide chemical is unsafe within the meaning of section 346a of this title.

1950—Subsec. (e). Act Mar. 16, 1950, added subsec. (e).

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment of subsec. (a)(2) of this section by Pub. L. 90-399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90-399, set out as an Effective Date note under section 360b of this title.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective, subject to the provisions of section 203 of Pub. L. 86-618, on July 12, 1960, see section 202 of Pub. L. 86-618, set out as an Effective Date of 1960 Amendment note under section 376 of this title.

EFFECTIVE DATE OF NEMATOCIDE, PLANT REGULATOR, DEFOLIANT, AND DESICCANT AMENDMENT OF 1959

Effective date of subsec. (a)(2) of this section as in force prior to July 22, 1954, with respect to particular commercial use of a nematocide, plant regulator, defoliant, or desiccant in or on a raw agricultural commodity made before Jan. 1, 1958, see section 3(b) of Pub. L. 86-139, Aug. 7, 1959, 73 Stat. 288.

EFFECTIVE DATE OF 1958 AMENDMENT

Section 6 of Pub. L. 85-929, as amended by Pub. L. 87-19, § 2, Apr. 7, 1961, 75 Stat. 42; Pub. L. 88-625, § 2, Oct. 3, 1964, 78 Stat. 1002, provided that:

"(a) Except as provided in subsections (b) and (c) of this section, this Act [sections 321(s) and (t), 321 note, 331(j), 451 note, and 348 of this title, and 210(g) of Title 42, The Public Health and Welfare] shall take effect on the date of its enactment [Sept. 6, 1958].

"(b) Except as provided in subsection (c) of this section, section 3 of this Act [amending subsec. (a) of this section and section 346(a) of this title] shall take effect on the one hundred and eightieth day after the date of enactment of this Act [Sept. 6, 1958].

"(c) With respect to any particular commercial use of a food additive, if such use was made of such additive before January 1, 1958, section 3 of this Act [amending subsec. (a) of this section and section 346(a) of this title] shall take effect—

"(1) Either (A) one year after the effective date established in subsection (b) of this section, or (B) at the end of such additional period (but not later than two years from such effective date established in subsection (b)) as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such an additional period, or

"(2) on the date on which an order with respect to such use under section 409 of the Federal Food, Drug, and Cosmetic Act [section 348 of this title] becomes effective,

whichever date first occurs. Whenever the Secretary has, pursuant to clause (1)(B) of this subsection, extended the effective date of section 3 of this Act [adding subsec. (a)(2)(C), (7) of this section] to March 5, 1961, or has on that date a request for such exten-

sion pending before him, with respect to any such particular use of a food additive, he may, notwithstanding the parenthetical time limitation in that clause, further extend such effective date, not beyond June 30, 1964, under the authority of that clause (but subject to clause (2)) with respect to such use of the additive (or a more limited specified use or uses thereof) if, in addition to making the findings required by clause (1)(B), he finds (i) that bona fide action to determine the applicability of such section 409 [section 348 of this title] to such use or uses, or to develop the scientific data necessary for action under such section, was commenced by an interested person before March 6, 1960, and was thereafter pursued with reasonable diligence, and (ii) that in the Secretary's judgment such extension is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary as a basis for action under such section 409 [section 348 of this title]: *Provided*, That if the Secretary has, pursuant to this sentence, granted an extension to June 30, 1964, he may, upon making the findings required by clause (1)(B) of this subsection and clauses (i) and (ii) of this sentence, further extend such effective date, but not beyond December 31, 1965. The Secretary may at any time terminate an extension so granted if he finds that it should not have been granted, or that by reason of a change in circumstances the basis for such extension no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such extension."

EFFECTIVE DATE OF 1954 AMENDMENT

Section 5 of act July 22, 1954, provided that:

"This Act [sections 321(q), (r), 342(a)(2), 346a and 346b of this title] shall take effect upon the date of its enactment [July 22, 1954], except that with respect to pesticide chemicals for which tolerances or exemptions have not been established under section 408 of the Federal Food, Drug, and Cosmetic Act [section 346a of this title], the amendment to section 402(a) of such Act [subsec. (a)(2) of this section] made by section 2 of this Act shall not be effective—

"(1) for the period of one year following the date of the enactment of this Act [July 22, 1954]; or

"(2) for such additional period following such period of one year, but not extending beyond two years after the date of the enactment of this Act [July 22, 1954] as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that conditions exist which necessitate the prescribing of such additional period."

EFFECTIVE DATE OF 1950 AMENDMENT

Amendment by act Mar. 16, 1950, effective July 1, 1950, see section 7 of act Mar. 16, 1950, set out as an Effective Date note under section 347 of this title.

EFFECTIVE DATE; POSTPONEMENT

Subsec. (c) of this section effective Jan. 1, 1940, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date; Postponement in Certain Cases note under section 301 of this title.

SHORT TITLE

Section 1 of Pub. L. 88-625, Oct. 3, 1964, 78 Stat. 1002, provided: "That this Act [which amended provisions set out as a note under this section and section 135 of Title 7, Agriculture] may be cited as the 'Food Additives Transitional Provisions Amendment of 1964'."

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

CROSS REFERENCES

Appropriations for establishing tolerances for pesticide chemicals, see section 346b of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 334, 346, 346a, 346b, 347b, 348, 360b, 376 of this title.

§ 343. Misbranded food

A food shall be deemed to be misbranded—

(a) False or misleading label

If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title.

(b) Offer for sale under another name

If it is offered for sale under the name of another food.

(c) Imitation of another food

If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) Misleading container

If its container is so made, formed, or filled as to be misleading.

(e) Package form

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this subsection reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) Prominence of information on label

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) Representation as to definition and standard of identity

If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341 of this title, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) Representation as to standards of quality and fill of container

If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 341 of this title, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 341 of this title, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) Label where no representation as to definition and standard of identity

If it is not subject to the provisions of subsection (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided*, That, to the extent that compliance with the requirements of clause (2) of this subsection is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) Representation for special dietary use

If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) Artificial flavoring, artificial coloring, or chemical preservatives

If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this subsection is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this subsection and subsections (g) and (i) of this section with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this subsection with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.

(*l*) Pesticide chemicals on raw agricultural commodities

If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the function of such chemical: *Provided, however*, That no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade.

(m) Color additives

If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 376 of this title.

(n) Packaging or labeling of drugs in violation of regulations

If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of title 15.

(June 25, 1938, ch. 675, § 403, 52 Stat. 1047; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; June 29, 1960, Pub. L. 86-537, § 1, 74 Stat. 251; July 12, 1960, Pub. L. 86-618, title I, § 102(a)(3), 74 Stat. 398; Dec. 30, 1970, Pub. L. 91-601, § 7(c), 84 Stat. 1763; Apr. 22, 1976, Pub. L. 94-278, title V, § 502(a)(1), 90 Stat. 411.)

AMENDMENTS

1976—Subsec. (a). Pub. L. 94-278 inserted "(1)" after "If" and inserted ", or (2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title" after "any particular".

1970—Subsec. (n). Pub. L. 91-601 added subsec. (n).

1960—Subsec. (k). Pub. L. 86-537, § 1(1), exempted pesticide chemicals when used in or on a raw agricultural commodity which is the produce of the soil.

Subsec. (*l*). Pub. L. 86-537, § 1(2), added subsec. (*l*).

Subsec. (m). Pub. L. 86-618 added subsec. (m).

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94-278 effective 180 days after Apr. 22, 1976, see section 502(c) of Pub. L. 94-278, set out as Effective Date of 1976 Amendment note under section 334 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91-601 effective Dec. 30, 1970, and regulations establishing special packaging standards effective no sooner than 180 days or later than one year from date regulations are final, or an earlier date published in Federal Register, see section 9 of Pub. L. 91-601, set out as an Effective Date note under section 1471 of Title 15, Commerce and Trade.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective, subject to the provisions of section 203 of Pub. L. 86-618, on July 12, 1960, see section 202 of Pub. L. 86-618, set out as an Effective Date of 1960 Amendment note under section 376 of this title.

EFFECTIVE DATE; POSTPONEMENT

Subsecs. (e)(1), (g) to (k) of this section effective Jan. 1, 1940 and such subsections effective July 1, 1940 as provided by regulations for certain lithographed labeling and containers bearing certain labeling, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date; Postponement in Certain Cases note under section 301 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to

the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

STATE OR TERRITORIAL REQUIREMENTS

Section 2 of Pub. L. 86-537 provided that: "Nothing in the amendments made by the first section of this Act [amending subsec. (k) and adding subsec. (*l*)] shall affect any requirement of the laws of any State or Territory."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 333, 334, 347, 350, 371 of this title.

§ 344. Emergency permit control

(a) Conditions on manufacturing, processing, etc., as health measure

Whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Secretary as provided by such regulations.

(b) Violation of permit; suspension and reinstatement

The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) Inspection of permit-holding establishments

Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

(June 25, 1938, ch. 675, § 404, 52 Stat. 1048; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 333, 334, 371 of this title.

§ 345. Regulations making exemptions

The Secretary shall promulgate regulations exempting from any labeling requirement of this chapter (1) small open containers of fresh fruits and fresh vegetables and (2) food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

(June 25, 1938, ch. 675, § 405, 52 Stat. 1049; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

§ 346. Tolerances for poisonous or deleterious substances in food; regulations

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title. While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 342(a) of this title. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(June 25, 1938, ch. 675, § 406, 52 Stat. 1049; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631;

Sept. 6, 1958, Pub. L. 85-929, § 3(c), 72 Stat. 1785; July 12, 1960, Pub. L. 86-618, title I, § 103(a)(1), 74 Stat. 398.)

AMENDMENTS

1960—Pub. L. 86-618 repealed former subsec. (b), which required the Secretary to promulgate regulations for the listing of coal-tar colors.

1958—Subsec. (a). Pub. L. 85-929 substituted "clause (2)(A)" for "clause (2)" in first sentence.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective, subject to the provisions of section 203 of Pub. L. 86-618, on July 12, 1960, see section 202 of Pub. L. 86-618, set out as an Effective Date of 1960 Amendment note under section 376 of this title.

EFFECTIVE DATE OF NEMATOCIDE, PLANT REGULATOR, DEFOLIANT, AND DESICCANT AMENDMENT OF 1959

Effective date of subsec. (a) of this section as in force prior to July 22, 1954, with respect to particular commercial use of a nematocide, plant regulator, defoliant, or desiccant in or on a raw agricultural commodity made before Jan. 1, 1958, see section 3(b) of Pub. L. 86-139, Aug. 7, 1959, 73 Stat. 288.

EFFECTIVE DATE OF 1958 AMENDMENT

Effective date of 1958 amendment of subsec. (a), see section 6(b), (c) of Pub. L. 85-929, set out as an Effective Date of 1958 Amendment note under section 342 of this title.

TRANSFER OF FUNCTIONS

All functions vested in the Secretary of Health, Education, and Welfare in establishing tolerances for pesticide chemicals under this section together with the authority to monitor compliance with the tolerances and the effectiveness of surveillance and enforcement and to provide technical assistance to the States and conduct research under this chapter and section 201 et seq. of Title 42, The Public Health and Welfare, were transferred to the Administrator of the Environmental Protection Agency by Reorg. Plan No. 3 of 1970, § 2(a)(4), eff. Dec. 2, 1970, 35 F.R. 15623, 84 Stat. 2086, set out in the Appendix to Title 5, Government Organization and Employees.

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

CROSS REFERENCES

Pesticide chemical regulations, see section 346a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 342, 346a, 371 of this title.

§ 346a. Tolerances for pesticide chemicals in or on raw agricultural commodities

(a) Conditions of safety

Any poisonous or deleterious pesticide chemical, or any pesticide chemical which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, added to a raw agricultural commodity, shall be deemed unsafe for the purposes of the application of clause (2) of section 342(a) of this title unless—

(1) a tolerance for such pesticide chemical in or on the raw agricultural commodity has been prescribed by the Administrator of the Environmental Protection Agency under this section and the quantity of such pesticide chemical in or on the raw agricultural commodity is within the limits of the tolerance so prescribed; or

(2) with respect to use in or on such raw agricultural commodity, the pesticide chemical has been exempted from the requirement of a tolerance by the Administrator under this section.

While a tolerance or exemption from tolerance is in effect for a pesticide chemical with respect to any raw agricultural commodity, such raw agricultural commodity shall not, by reason of bearing or containing any added amount of such pesticide chemical, be considered to be adulterated within the meaning of clause (1) of section 342(a) of this title.

(b) Establishment of tolerances

The Administrator shall promulgate regulations establishing tolerances with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, to the extent necessary to protect the public health. In establishing any such regulation, the Administrator shall give appropriate consideration, among other relevant factors, (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious; and (3) to the opinion submitted with a certification of usefulness under subsection (*l*) of this section. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section. In carrying out the provisions of this section relating to the establishment of tolerances, the Administrator may establish the tolerance applicable with respect to the use of any pesticide chemical in or on any raw agricultural commodity at zero level if the scientific data before the Administrator does not justify the establishment of a greater tolerance.

(c) Exemptions

The Administrator shall promulgate regulations exempting any pesticide chemical from the necessity of a tolerance with respect to use in or on any or all raw agricultural commodities when such a tolerance is not necessary to protect the public health. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section.

(d) Regulations pursuant to petition; publication of notice; time for issuance; referral to advisory committees; effective date; hearings

(1) Any person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.] may file with the Administrator a petition proposing the issuance of a regulation establishing a tolerance for a pesticide chemical which constitutes, or is an ingredient of, such pesticide, or exempting the pesticide chemical

from the requirement of a tolerance. The petition shall contain data showing—

(A) the name, chemical identity, and composition of the pesticide chemical;

(B) the amount, frequency, and time of application of the pesticide chemical;

(C) full reports of investigations made with respect to the safety of the pesticide chemical;

(D) the results of tests on the amount of residue remaining, including a description of the analytical methods used;

(E) practicable methods for removing residue which exceeds any proposed tolerance;

(F) proposed tolerances for the pesticide chemical if tolerances are proposed; and

(G) reasonable grounds in support of the petition.

Samples of the pesticide chemical shall be furnished to the Administrator upon request. Notice of the filing of such petition shall be published in general terms by the Administrator within thirty days after filing. Such notice shall include the analytical methods available for the determination of the residue of the pesticide chemical for which a tolerance or exemption is proposed.

(2) Within ninety days after a certification of usefulness under subsection (*l*) of this section with respect to the pesticide chemical named in the petition, the Administrator shall, after giving due consideration to the data submitted in the petition or otherwise before him, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful, or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes,

unless within such ninety-day period the person filing the petition requests that the petition be referred to an advisory committee or the Administrator within such period otherwise deems such referral necessary, in either of which events the provisions of paragraph (3) of this subsection shall apply in lieu hereof.

(3) In the event that the person filing the petition requests, within ninety days after a certification of usefulness under subsection (*l*) of this section with respect to the pesticide chemical named in the petition, that the petition be referred to an advisory committee, or in the event the Administrator within such period otherwise deems such referral necessary, the Administrator shall forthwith submit the petition and other data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Administrator and other data before it, certify to the Administrator a report and recommendations on the proposal in the petition to the Administrator, together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Administrator shall, after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful; or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes.

(4) The regulations published under paragraph (2) or (3) of this subsection will be effective upon publication.

(5) Within thirty days after publication, any person adversely affected by a regulation published pursuant to paragraph (2) or (3) of this subsection, or pursuant to subsection (e) of this section, may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. A copy of the objections filed by a person other than the petitioner shall be served on the petitioner, if the regulation was issued pursuant to a petition. The petitioner shall have two weeks to make a written reply to the objections. The Administrator shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 556(d) of title 5. The National Academy of Sciences shall designate a member of the advisory committee to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Administrator, the petitioner, or the officer conducting the hearing: *Provided*, That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Administrator shall act upon such objections and by order make public a regulation. Such regulation shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Administrator by an advisory committee, and shall set forth detailed findings of fact upon which the regulation is based. No such order shall take effect prior to the ninetieth day after its publication, unless the Administrator finds that emergency conditions exist necessitating an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.

(e) Regulations pursuant to Administrator's proposals

The Administrator may at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of

a tolerance. Thirty days after publication of such a proposal, the Administrator may by order publish a regulation based upon the proposal which shall become effective upon publication unless within such thirty-day period a person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.] containing the pesticide chemical named in the proposal, requests that the proposal be referred to an advisory committee. In the event of such a request, the Administrator shall forthwith submit the proposal and other relevant data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Administrator and other data before it, certify to the Administrator a report and recommendations on the proposal together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Administrator may, after giving due consideration to all data before him, including such report, recommendations, underlying data and statement, by order publish a regulation establishing a tolerance for the pesticide chemical named in the proposal or exempting it from the necessity of a tolerance which shall become effective upon publication. Regulations issued under this subsection shall upon publication be subject to paragraph (5) of subsection (d) of this section.

(f) Data submitted as confidential

All data submitted to the Administrator or to an advisory committee in support of a petition under this section shall be considered confidential by the Administrator and by such advisory committee until publication of a regulation under paragraph (2) or (3) of subsection (d) of this section. Until such publication, such data shall not be revealed to any person other than those authorized by the Administrator or by an advisory committee in the carrying out of their official duties under this section.

(g) Advisory committees; appointment; composition; compensation; clerical assistance

Whenever the referral of a petition or proposal to an advisory committee is requested under this section, or the Administrator otherwise deems such referral necessary the Administrator shall forthwith appoint a committee of competent experts to review the petition or proposal and to make a report and recommendations thereon. Each such advisory committee shall be composed of experts, qualified in the subject matter of the petition and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Administrator. Members of an advisory committee shall receive compensation and travel expenses in accordance with section 376(b)(5)(D) of this title. The members shall not be subject to any other provision of law regarding the appointment and compensation of employees of the United States. The Administrator shall furnish the Committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

(h) Right of consultation

A person who has filed a petition or who has requested the referral of a proposal to an advisory committee in accordance with the provisions of this section, as well as representatives of the Environmental Protection Agency, shall have the right to consult with any advisory committee provided for in subsection (g) of this section in connection with the petition or proposal.

(i) Judicial review

(1) In a case of actual controversy as to the validity of any order under subsections (d)(5), (e), or (*l*) of this section any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) In the case of a petition with respect to an order under subsection (d)(5) or (e) of this section, a copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by him for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Administrator with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole, including any report and recommendation of an advisory committee.

(3) In the case of a petition with respect to an order under subsection (*l*) of this section, a copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by him for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Administrator with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Administrator and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may

seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Administrator may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order. The courts shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(j) Temporary tolerances

The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.] or upon his own initiative, establish a temporary tolerance for the pesticide chemical for the uses covered by the permit whenever in his judgment such action is deemed necessary to protect the public health, or may temporarily exempt such pesticide chemical from a tolerance. In establishing such a tolerance, the Administrator shall give due regard to the necessity for experimental work in developing an adequate, wholesome, and economical food supply and to the limited hazard to the public health involved in such work when conducted in accordance with applicable regulations under the Federal Insecticide, Fungicide, and Rodenticide Act.

(k) Regulations based on public hearings before January 1, 1953

Regulations affecting pesticide chemicals in or on raw agricultural commodities which are promulgated under the authority of section 346(a) of this title upon the basis of public hearings instituted before January 1, 1953, in accordance with section 371(a) of this title, shall be deemed to be regulations under this section and shall be subject to amendment or repeal as provided in subsection (m) of this section.

(l) Pesticides under Federal Insecticide, Fungicide, and Rodenticide Act; functions of Administrator of the Environmental Protection Agency; certifications; hearing; time limitation; opinion; regulations

The Administrator, upon request of any person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.], and whose request is accompanied by a copy of a petition filed by such person under subsection (d)(1) of this section with respect to a pesticide chemical which constitutes, or is an ingredient of, such pesticide, shall, within thirty days or within sixty days if upon notice prior to the termination of such thirty days the Administrator deems it necessary to postpone action for such period, on the basis of data before him, either—

(1) certify that such pesticide chemical is useful for the purpose for which a tolerance or exemption is sought; or

(2) notify the person requesting the certification of his proposal to certify that the pesticide chemical does not appear to be useful for the purpose for which a tolerance or exemption is sought, or appears to be useful for only some of the purposes for which a tolerance or exemption is sought.

In the event that the Administrator takes the action described in clause (2) of the preceding sentence, the person requesting the certification, within one week after receiving the proposed certification, may either (A) request the Administrator to certify on the basis of the proposed certification; (B) request a hearing on the proposed certification or the parts thereof objected to; or (C) request both such certification and such hearing. If no such action is taken, the Administrator may by order make the certification as proposed. In the event that the action described in clause (A) or (C) is taken, the Administrator shall by order make the certification as proposed with respect to such parts thereof as are requested. It[1] the event a hearing is requested, the Administrator shall provide opportunity for a prompt hearing. The certification of the Administrator as the result of such hearing shall be made by order and shall be based only on substantial evidence of record at the hearing and shall set forth detailed findings of fact. In no event shall the time elapsing between the making of a request for a certification under this subsection and final certification by the Administrator exceed one hundred and sixty days. The Administrator shall submit with any certification of usefulness under this subsection an opinion, based on the data before him, whether the tolerance or exemption proposed by the petitioner reasonably reflects the amount of residue likely to result when the pesticide chemical is used in the manner proposed for the purpose for which the certification is made. The Administrator, after due notice and opportunity for public hearing, is authorized to promulgate rules and regulations for carrying out the provisions of this subsection.

(m) Amendment of regulations

The Administrator shall prescribe by regulations the procedure by which regulations under this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of regulations establishing tolerances, including the appointment of advisory committees and the procedure for referring petitions to such committees.

(n) Guaranties

The provisions of section 333(c) of this title with respect to the furnishing of guaranties shall be applicable to raw agricultural commodities covered by this section.

(o) Payment of fees; services or functions as conditioned on; waiver or refund of fees

The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be

[1] So in original. Probably should read "In".

sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. Under such regulations, the performance of the Administrator's services or other functions pursuant to this section, including any one or more of the following, may be conditioned upon the payment of such fees: (1) The acceptance of filing of a petition submitted under subsection (d) of this section; (2) the promulgation of a regulation establishing a tolerance, or an exemption from the necessity of a tolerance, under this section, or the amendment or repeal of such a regulation; (3) the referral of a petition or proposal under this section to an advisory committee; (4) the acceptance for filing of objections under subsection (d)(5) of this section; or (5) the certification and filing in court of a transcript of the proceedings and the record under subsection (i)(2) of this section. Such regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such waiver or refund is equitable and not contrary to the purposes of this subsection.

(June 25, 1938, ch. 675, § 408, as added July 22, 1954, ch. 559, § 3, 68 Stat. 511, and amended Aug. 28, 1958, Pub. L. 85-791, § 20, 72 Stat. 947; Oct. 30, 1970, Pub. L. 91-515, title VI, § 601(d)(1), 84 Stat. 1311; 1970 Reorg. Plan No. 3, § 2(a)(4), (8)(ii), eff. Dec. 2, 1970, 35 F.R. 15623, 84 Stat. 2086; Nov. 18, 1971, Pub. L. 92-157, title III, § 303(a), 85 Stat. 464; Oct. 21, 1972, Pub. L. 92-516, § 3(3), 86 Stat. 998.)

REFERENCES IN TEXT

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsecs. (d), (e), (j), and (*l*), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92-516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (§ 136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables volume.

CODIFICATION

"Section 556(d) of title 5" was substituted for "section 7(c) of the Administrative Procedure Act (5 U.S.C. sec. 1006(c))", in subsec. (d), on authority of section 7(b) of Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 631, section 1 of which enacted Title 5, Government Organization and Employees.

AMENDMENTS

1972—Subsecs. (d)(1), (e), (*l*). Pub. L. 92-516 substituted references to pesticide for references to economic poison wherever appearing therein.

1971—Subsec. (g). Pub. L. 92-157 struck out ", which the Secretary shall by rules and regulations prescribe," appearing following "as compensation for their services a reasonable per diem" prior to amendment in 1970, by Pub. L. 91-515, which overlooked such language when amending subsec. (g) as provided in 1970 Amendment note.

1970—Subsec. (g). Pub. L. 91-515 substituted provisions authorizing members of an advisory committee to receive compensation and travel expenses in accordance with section 376(b)(5)(D) of this title, for provisions authorizing such members to receive as compensation a reasonable per diem for time actually spent on committee work, and necessary traveling and subsistence expenses while serving away from their places of residence.

1958—Subsec. (i)(2). Pub. L. 85-791, § 20(a), in first sentence, substituted "transmitted by the clerk of the court to the Secretary, or" for "served upon the Secretary, or upon", substituted "file in the court the record of the proceedings" for "certify and file in the court a transcript of the proceedings and the record", and inserted "as provided in section 2112 of title 28", and which, in second sentence, substituted "the filing of such petition" for "such filing".

Subsec. (i)(3). Pub. L. 85-791, § 20(b), in first sentence, substituted "transmitted by the clerk of the court to the Secretary of Agriculture, or" for "served upon the Secretary of Agriculture, or upon", substituted "file in the court the record of the proceedings" for "certify and file in the court a transcript of the proceedings and the record", and inserted "as provided in section 2112 of title 28", and, in second sentence, substituted "the filing of such petition" for "such filing".

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92-516 effective at the close of Oct. 21, 1972, except if regulations are necessary for the implementatin of any provision that becomes effective on Oct. 21, 1972, and continuation in effect of subchapter I of chapter 6 of Title 7, and regulations thereunder, relating to the control of economic poisons, as in existence prior to Oct. 21, 1972, until superseded by provisions of Pub. L. 92-516 and regulations thereunder, see section 4 of Pub. L. 92-516, set out as an Effective Date note under section 136 of Title 7, Agriculture.

TRANSFER OF FUNCTIONS

"Administrator of the Environmental Protection Agency" was substituted, in subsecs. (a) to (j), (*l*), (m), and (*o*), for "Secretary of Health, Education, and Welfare" and in subsecs. (b), (d), (i), and (*l*), for "Secretary of Agriculture" pursuant to Reorg. Plan No. 3 of 1970, set out in the Appendix to Title 5, Government Organization and Employees, which transferred to the Administrator of the Environmental Protection Agency all functions vested in the Secretary of Health, Education, and Welfare in establishing tolerances for pesticide chemicals under this section together with the authority to monitor compliance with the tolerances and the effectiveness of surveillance and enforcement and to provide technical assistance to the States and conduct research under this chapter and section 201 et seq. of Title 42, The Public Health and Welfare, and which also transferred to the Administrator of the Environmental Protection Agency the functions of Agriculture Department and the Secretary of Agriculture under subsec. (*l*) of this section.

CROSS REFERENCES

Federal Advisory Committee Act, see Appendix to Title 5, Government Organization and Employees.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 342, 346b, 453, 601, 1033 of this title.

§ 346b. Authorization of appropriations

There are authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, such sums as may be necessary for the purpose and administration of sections 321(q), (r), 342(a)(2), and 346a of this title.

(July 22, 1954, ch. 559, § 4, 68 Stat. 517.)

CODIFICATION

Section was not enacted as a part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§ 347. Intrastate sales of colored oleomargarine

(a) Law governing

Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the

same manner and to the same extent to the provisions of this chapter as if it had been introduced in interstate commerce.

(b) Labeling and packaging requirements

No person shall sell, or offer for sale, colored oleomargarine or colored margarine unless—

(1) such oleomargarine or margarine is packaged,

(2) the net weight of the contents of any package sold in a retail establishment is one pound or less,

(3) there appears on the label of the package (A) the word "oleomargarine" or "margarine" in type or lettering at least as large as any other type or lettering on such label, and (B) a full and accurate statement of all the ingredients contained in such oleomargarine or margarine, and

(4) each part of the contents of the package is contained in a wrapper which bears the word "oleomargarine" or "margarine" in type or lettering not smaller than 20-point type.

The requirements of this subsection shall be in addition to and not in lieu of any of the other requirements of this chapter.

(c) Sales in public eating places

No person shall possess in a form ready for serving colored oleomargarine or colored margarine at a public eating place unless a notice that oleomargarine or margarine is served is displayed prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by the ordinary individual being served in such eating place or is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items. No person shall serve colored oleomargarine or colored margarine at a public eating place, whether or not any charge is made therefor, unless (1) each separate serving bears or is accompanied by labeling identifying it as oleomargarine or margarine, or (2) each separate serving thereof is triangular in shape.

(d) Exemption from labeling requirements

Colored oleomargarine or colored margarine when served with meals at a public eating place shall at the time of such service be exempt from the labeling requirements of section 343 of this title (except subsection (a) and (f) of section 343 of this title) if it complies with the requirements of subsection (b) of this section.

(e) Color content of oleomargarine

For the purpose of this section colored oleomargarine or colored margarine is oleomargarine or margarine having a tint or shade containing more than one and six-tenths degrees of yellow, or of yellow and red collectively, but with an excess of yellow over red, measured in terms of Lovibond tintometer scale or its equivalent.

(June 25, 1938, ch. 675, § 407, as added Mar. 16, 1950, ch. 61, § 3(c), 64 Stat. 20.)

EFFECTIVE DATE

Section 7 of act Mar. 16, 1950, provided that: "This Act [enacting sections 347 to 347b of this title, and amending sections 331 and 342 of this title and sections 45 and 55 of Title 15, Commerce and Trade] shall become effective on July 1, 1950."

TRANSFER OF APPROPRIATIONS

Section 5 of act Mar. 16, 1950, provided that: "So much of the unexpended balances of appropriations, allocations, or other funds (including funds available for the fiscal year ending June 30, 1950) for the use of the Bureau of Internal Revenue of the Treasury Department in the exercise of functions under the Oleomargarine Tax Act (26 U.S.C., § 2300, subchapter A) [now section 4591 et seq. of Title 26, Internal Revenue Code], as the Director of the Bureau of the Budget [now Director of the Office of Management and Budget] may determine, shall be transferred to the Federal Security Agency (Food and Drug Administration) [now the Department of Health, Education, and Welfare] for use in the enforcement of this Act [sections 331(m), 342(e), and 347 to 347b of this title and sections 45(*l*) and 55(a), (f) of Title 15, Commerce and Trade.]"

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 347b of this title.

§ 347a. Congressional declaration of policy regarding oleomargarine sales

The Congress finds and declares that the sale, or the serving in public eating places, of colored oleomargarine or colored margarine without clear identification as such or which is otherwise adulterated or misbranded within the meaning of this chapter depresses the market in interstate commerce for butter and for oleomargarine or margarine clearly identified and neither adulterated nor misbranded, and constitutes a burden on interstate commerce in such articles. Such burden exists, irrespective of whether such oleomargarine or margarine originates from an interstate source or from the State in which it is sold.

(Mar. 16, 1950, ch. 61, § 3(a), 64 Stat. 20.)

CODIFICATION

Section was not enacted as a part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

EFFECTIVE DATE

Section effective July 1, 1950, see section 7 of act Mar. 16, 1950, set out as an Effective Date note under section 347 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 347b of this title.

§ 347b. Contravention of State laws

Nothing in this Act shall be construed as authorizing the possession, sale, or serving of colored oleomargarine or colored margarine in any State or Territory in contravention of the laws of such State or Territory.

(Mar. 16, 1950, ch. 61, § 6, 64 Stat. 22.)

REFERENCES IN TEXT

This Act, referred to in text, is act Mar. 16, 1950, ch. 61, 64 Stat. 20, which is classified to sections 331, 342, 347 to 347b of this title, and sections 45 and 55 of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Tables volume.

CODIFICATION

Section was not enacted as a part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

EFFECTIVE DATE

Section effective July 1, 1950, see section 7 of act Mar. 16, 1950, set out as an Effective Date note under section 347 of this title.

§ 348. Food additives

(a) Unsafe food additives; exception for conformity with exemption or regulation

A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 342(a) of this title, unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 342(a) of this title.

(b) Petition for regulation prescribing conditions of safe use; contents; description of production methods and controls; samples; notice of regulation

(1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

(2) Such petition shall, in addition to any explanatory or supporting data, contain—

(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, without disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for, the production of such additive.

(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

(c) Approval or denial of petition; time for issuance of orders; evaluation of data; factors

(1) The Secretary shall—

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) The order required by paragraph (1)(A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g) of this section) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal; or

(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this chapter or would otherwise result in adulteration or in mis-

branding of food within the meaning of this chapter.

(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

(d) Regulation issued on Secretary's initiative

The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

(e) Publication and effective date of orders

Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f) of this section.

(f) Objections and public hearing; basis and contents of order; statement

(1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(g) Judicial review

(1) In a case of actual controversy as to the validity of any order issued under subsection (f) of this section, including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28. Upon the filing of such petition the court shall have jurisdiction, which upon the filing of the record with it shall be exclusive, to affirm or set aside the order complained of in whole or in part. Until the filing of the record the Secretary may modify or set aside his order. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f)(2) of this section.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commence-

ment of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

(h) Amendment or repeal of regulations

The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.

(i) Exemptions for investigational use

Without regard to subsections (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

(June 25, 1938, ch. 675, § 409, as added Sept. 6, 1958, Pub. L. 85-929, § 4, 72 Stat. 1785, and amended June 29, 1960, Pub. L. 86-546, § 2, 74 Stat. 255; Oct. 10, 1962, Pub. L. 87-781, title I, § 104(f)(1), 76 Stat. 785.)

AMENDMENTS

1962—Subsec. (c)(3)(A). Pub. L. 87-781 excepted the proviso from applying to use of a substance as an ingredient of feed for animals raised for food production, if under conditions of use specified in proposed labeling, and which conditions are reasonably certain to be followed in practice, such additive will not adversely affect the animals and no residue will be found in any edible portion of such animal after slaughter, or in any food from the living animal.

1960—Subsec. (g)(2). Pub. L. 86-546 substituted "forthwith transmitted by the clerk of the court to the Secretary, or any officer" for "served upon the Secretary, or upon any officer", "shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28" for "shall certify and file in the court a transcript of the proceedings and the record on which he based his order", and "Upon the filing of such petition the court shall have jurisdiction, which upon the filing of the record with it shall be exclusive," for "Upon such filing, the court shall have exclusive jurisdiction", and inserted sentence authorizing the Secretary to modify or set aside his order until the filing of the record.

EFFECTIVE DATE OF 1962 AMENDMENT; EXCEPTIONS

Amendment by Pub. L. 87-781 effective on Oct. 10, 1962, see section 107 of Pub. L. 87-781, set out as an Effective Date of 1962 Amendment note under section 321 of this title.

EFFECTIVE DATE

Section effective Sept. 6, 1958, see section 6(a) of Pub. L. 85-929, set out as an Effective Date of 1958 Amendment note under section 342 of this title.

TRANSFER OF FUNCTIONS

All functions vested in the Secretary of Health, Education, and Welfare in establishing tolerances for pesticide chemicals under this section together with the authority to monitor compliance with the tolerances and the effectiveness of surveillance and enforcement and to provide technical assistance to the States and conduct research under this chapter and section 201 et seq. of Title 42, The Public Health and Welfare, were transferred to the Administrator of the Environmental Protection Agency by Reorg. Plan No. 3 of 1970, § 2(a)(4), eff. Dec. 2, 1970, 35 F.R. 15623, 84 Stat. 2086, set out in the Appendix to Title 5, Government Organization and Employees.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 331, 342, 376, 453, 601, 1033 of this title; title 15 section 1262.

§ 349. Bottled drinking water standards; publication in Federal Register

Whenever the Administrator of the Environmental Protection Agency prescribes interim or revised national primary drinking water regulations under section 300g-1 of title 42, the Secretary shall consult with the Administrator and within 180 days after the promulgation of such drinking water regulations either promulgate amendments to regulations under this chapter applicable to bottled drinking water or publish in the Federal Register his reasons for not making such amendments.

(June 25, 1938, ch. 675, § 410, as added Dec. 16, 1974, Pub. L. 93-523, § 4, 88 Stat. 1694.)

§ 350. Vitamins and minerals

(a) Authority and limitations of Secretary; applicability

(1) Except as provided in paragraph (2)—

(A) the Secretary may not establish, under section 321(n), 341, or 343 of this title, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful;

(C) the Secretary may not limit, under section 321(n), 341, or 343 of this title, the combination or number of any synthetic or natural—

(i) vitamin,

(ii) mineral, or

(iii) other ingredient of food,

within a food to which this section applies.

(2) Paragraph (1) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this subparagraph, the term "children" means individuals who are under the age of twelve years.

(b) Labeling and advertising requirements for foods

(1) A food to which this section applies shall not be deemed under section 343 of this title to be misbranded solely because its label bears, in accordance with section 343(i)(2) of this title, all the ingredients in the food or its advertising contains references to ingredients in the food which are not vitamins or minerals.

(2)(A) The labeling for any food to which this section applies may not list its ingredients which are not vitamins or minerals (i) except as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 343 of this title. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be estab-

lished by regulations promulgated by the Secretary.

(B) Notwithstanding the provisions of subparagraph (A), the labeling and advertising for any food to which this section applies may not give prominence to or emphasize ingredients which are not—

(i) vitamins,

(ii) minerals, or

(iii) represented as a source of vitamins or minerals.

(c) Definitions

(1) For purposes of this section, the term "food to which this section applies" means a food for humans which is a food for special dietary use—

(A) which is or contains any natural or synthetic vitamin or mineral, and

(B) which—

(i) is intended for ingestion in tablet, capsule, or liquid form, or

(ii) if not intended for ingestion in such a form, does not simulate and is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

(2) For purposes of paragraph (1)(B)(i), a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

(3) For purposes of paragraph (1) and of section 343(j) of this title insofar as that section is applicable to food to which this section applies, the term "special dietary use" as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

(B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

(June 25, 1938, ch. 675, § 411, as added Apr. 22, 1976, Pub. L. 94-278, title V, § 501(a), 90 Stat. 410.)

AMENDMENT OF INCONSISTENT REGULATIONS BY SECRETARY

Section 501(b) of Pub. L. 94-278, provided that: "The Secretary of Health, Education, and Welfare shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act [this chapter] which is inconsistent with section 411 of such Act [section 350 of this title] (as added by subsection (a)) and such amendments shall be promulgated in accordance with section 553 of title 5, United States Code."

SUBCHAPTER V—DRUGS AND DEVICES

§ 351. Adulterated drugs and devices

A drug or device shall be deemed to be adulterated—

(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufactuing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 376(a) of this title, or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 376(a) of this title; or (5) if it is a new animal drug which is unsafe within the meaning of section 360b of this title; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 360b of this title.

(b) Strength, quality, or purity differing from official compendium

If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this subsection, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this subsection because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both

the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(c) Misrepresentation of strength, etc., where drug is unrecognized in compendium

If it is not subject to the provisions of subsection (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) Mixture with or substitution of another substance

If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

(e) Devices not in conformity with performance standards

If it is, or purports to be or is represented as, a device which is subject to a performance standard established under section 360d of this title unless such device is in all respects in conformity with such standard.

(f) Certain class III devices

(1) If it is a class III device—

(A)(i) which is required by a regulation promulgated under subsection (b) of section 360e of this title to have an approval under such section of an application for premarket approval and which is not exempt from section 360e of this title under section 360j(g) of this title, and

(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the Secretary within the ninety-day period beginning on the date of the promulgation of such regulation, or

(II) for which such an application was filed and approval of the application has been denied or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

(B)(i) which was classified under section 360c(f) of this title into class III, which under section 360e(a) of this title is required to have in effect an approved application for premarket approval, and which is not exempt from section 360e of this title under section 360j(g) of this title, and

(ii) which does not have such an application in effect; or

(C) which was classified under section 360j(*l*) of this title into class III, which under such section is required to have in effect an approved application under section 360e of this title, and which does not have such an application in effect.

(2)(A) In the case of a device classified under section 360c(f) of this title into class III and intended solely for investigational use, paragraph (1)(B) shall not apply with respect to such device during the period ending on the ninetieth day after the date of the promulgation of the regulations prescribing the procedures and conditions required by section 360j(g)(2) of this title.

(B) In the case of a device subject to a regulation promulgated under subsection (b) of section 360e of this title, paragraph (1) shall not apply with respect to such device during the period ending—

(i) on the last day of the thirtieth calendar month beginning after the month in which the classification of the device in class III became effective under section 360c of this title, or

(ii) on the ninetieth day after the date of the promulgation of such regulation,

whichever occurs later.

(g) Banned devices

If it is a banned device.

(h) Manufacture, packing, storage, or installation of device not in conformity with applicable requirements or conditions

If it is a device and the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 360j(f)(1) of this title or an applicable condition prescribed by an order under section 360j(f)(2) of this title.

(i) Failure to comply with requirements under which device was exempted for investigational use

If it is a device for which an exemption has been granted under section 360j(g) of this title for investigational use and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section.

(June 25, 1938, ch. 675, § 501, 52 Stat. 1049; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; July 12, 1960, Pub. L. 86-618, title I, § 102(b)(1), 74 Stat. 398; Oct. 10, 1962, Pub. L. 87-781, title I, § 101, 76 Stat. 780; July 13, 1968, Pub. L. 90-399, § 101(a), 82 Stat. 343; May 28, 1976, Pub. L. 94-295, §§ 3(d), 9(b)(1), 90 Stat. 576, 583.)

AMENDMENTS

1976—Subsec. (a). Pub. L. 94-295, § 9(b)(1), substituted "(3) if its" for "(3) if it is a drug and its" in cl. (3), substituted "(4) if (A) it bears or contains" for "(4) if (A) it is a drug which bears or contains" in cl. (4)(A), and substituted "drugs or devices" for "drugs" in cl. (4)(B).

Subsecs. (e) to (i). Pub. L. 94-295, § 3(d), added subsecs. (e) to (i).

1968—Subsec. (a). Pub. L. 90-399 added cls. (5) and (6).

1962—Subsec. (a). Pub. L. 87-781 designated existing provisions of cl. (2) as (A) and added (B).

1960—Subsec. (a). Pub. L. 86-618 substituted provisions in cl. (4) relating to unsafe color additives for provisions which related to a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 354 of this title.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment of subsec. (a) of this section by Pub. L. 90-399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90-399, set out as an Effective Date note under section 360b of this title.

EFFECTIVE DATE OF 1962 AMENDMENT; EXCEPTIONS

Amendment by Pub. L. 87-781 effective on the first day of the seventh calendar month following Oct. 1962, see section 107 of Pub. L. 87-781, set out as an Effective Date of 1962 Amendment note under section 321 of this title.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective, subject to the provisions of section 203 of Pub. L. 86-618, on July 12, 1960, see section 202 of Pub. L. 86-618, set out as an Effective Date of 1960 Amendment note under section 376 of this title.

EFFECTIVE DATE; POSTPONEMENT

Subsec. (a)(4) of this section effective Jan. 1, 1940, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date; Postponement in Certain Cases note under section 301 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 334, 356, 357, 360b, 360c, 360j, 371, 376 of this title.

§ 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded—

(a) False or misleading label

If its labeling is false or misleading in any particular.

(b) Package form; contents of label

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this subsection reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) Prominence of information on label

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) Habit forming substances

If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, betaeucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

(e) Designation of drugs or devices by established names

(1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (3)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury ouabain strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein; *Provided*, That the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs; and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided*, That to the extent that compliance with the requirements of clause (A)(ii) or clause (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(2) If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name (as defined in subparagraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(3) As used in subparagraph (1), the term "established name", with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 358 of this title, or (B), if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient: *Provided further*, That where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply.

(4) As used in subparagraph (2), the term "established name" with respect to a device means (A) the applicable official name of the device designated pursuant to section 358 of this title, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.

(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided,* That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

(g) Representations as recognized drug; packing and labeling; inconsistent requirements for designation of drug

If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: *Provided,* That the method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not those of the United States Pharmacopoeia: *Provided further,* That, in the event of inconsistency between the requirements of this subsection and those of subsection (e) of this section as to the name by which the drug or its ingredients shall be designated, the requirements of subsection (e) of this section shall prevail.

(h) Deteriorative drugs; packing and labeling

If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) Drug; misleading container; imitation; offer for sale under another name

(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) Health-endangering when used as prescribed

If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(k) Insulin not properly certified

If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 356 of this title, and (2) such certificate or release is in effect with respect to such drug.

(l) Antibiotic drugs improperly certified

If it is, or purports to be, or is represented as a drug (except a drug for use in animals other than man) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 357 of this title, and (2) such certificate or release is in effect with respect to such drug: *Provided,* That this subsection shall not apply to any drug or class of drugs exempted by regulations promulgated under section 357(c) or (d) of this title.

(m) Color additives; packing and labeling

If it is a color additive the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations issued under section 376 of this title.

(n) Prescription drug advertisements; established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling

In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under subsection (e) of this section, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 371(e) of this title: *Provided,* That (A) except in extraordinary circumstances, no regulation issued under this subsection shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this subsection applicable to advertisements of prescription drugs, shall with respect to the matters specified in this subsection or covered by such regulations, be subject to the provisions of sections

52 to 57 of title 15. This subsection (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 321(m) of this title.

(o) Drugs or devices from nonregistered establishments

If it was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered under section 360 of this title, if it was not included in a list required by section 360(j) of this title, if a notice or other information respecting it was not provided as required by such section or section 360(k) of this title, or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 360(e) of this title as the Secretary by regulation requires.

(p) Packaging or labeling of drugs in violation of regulations

If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of title 15.

(q) Restricted devices using false or misleading advertising or used in violation of regulations

In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title.

(r) Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter

In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing. Except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 52 through 55 of title 15. This paragraph shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 321(m) of this title.

(s) Devices subject to performance standards not bearing requisite labeling

If it is a device subject to a performance standard established under section 360d of this title, unless it bears such labeling as may be prescribed in such performance standard.

(t) Devices for which there has been a failure or refusal to give required notification or to furnish required material or information

If it is a device and there was a failure or refusal (1) to comply with any requirement prescribed under section 360h of this title respecting the device, or (2) to furnish any material or information required by or under section 360i of this title respecting the device.

(June 25, 1938, ch. 675, § 502, 52 Stat. 1050; June 23, 1939, ch. 242, § 3, 53 Stat. 854; 1940 Reorg. Plan No. IV, §§ 12, 13, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; Dec. 22, 1941, ch. 613, § 2, 55 Stat. 851; July 6, 1945, ch. 281, § 2, 59 Stat. 463; Mar. 10, 1947, ch. 16, § 2, 61 Stat. 11; July 13, 1949, ch. 305, § 1, 63 Stat. 409; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 5, 1953, ch. 334, § 1, 67 Stat. 389; July 12, 1960, Pub. L. 86-618, title I, § 102(b)(2), 74 Stat. 398; Oct. 10, 1962, Pub. L. 87-781, title I, §§ 105(c), 112(a), (b), 131(a), title III, § 305, 76 Stat. 785, 790, 791, 795; July 13, 1968, Pub. L. 90-399, § 105(a), 82 Stat. 352; Dec. 30, 1970, Pub. L. 91-601, § 7(d), 84 Stat. 1673; May 28, 1976, Pub. L. 94-295, §§ 3(e), 4(b)(2), 5(a), 9(b)(2), 90 Stat. 577, 580, 583.)

AMENDMENTS

1976—Subsec. (e). Pub. L. 94-295, § 5(a), substituted "subparagraph (3)" for "subparagraph (2)" in par. (1), added par. (2), redesignated former par. (2) as (3) and in par. (3) as so redesignated substituted "subparagraph (1)" for "this paragraph (e)", and added par. (4).

Subsec. (j). Pub. L. 94-295, § 3(e)(2), substituted "dosage or manner," for "dosage,".

Subsec. (m). Pub. L. 94-295, § 9(b)(2), substituted "the intended use of which is for" for "the intended use of which in or on drugs is for".

Subsec. (o). Pub. L. 94-295, § 4(b)(2), substituted "If it was manufactured" for "If it is a drug and was manufactured" and added ", if it was not included in a list required by section 360(j) of this title, if a notice or other information respecting it was not provided as required by such section or section 360(k) of this title, or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 360(e) of this title as the Secretary by regulation requires".

Subsecs. (q) to (t). Pub. L. 94-295, § 3(e)(1), added subsecs. (q) to (t).

1970—Subsec. (p). Pub. L. 91-601 added subsec. (p).

1968—Subsec. (l). Pub. L. 90-399 inserted "(except a drug for use in animals other than man)" following "represented as a drug".

1962—Subsec. (e). Pub. L. 87-781, § 112(a), designated existing provisions as par. (1), substituted ", unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in par. (2) of this subsection) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity" for "and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name", and "the established name" for "the name", provided that the requirement for stating the quantity of active ingredients, other than those speci-

fied in this subsection, applies only to prescription drugs, and that the established name of a drug on a label is to be printed prominently and in type at least half as large as used for any proprietary designation, and added par. (2) defining "established name".

Subsec. (g). Pub. L. 87-781, § 112(b), provided that if there is an inconsistency between the provisions of this subsection and those of subsec. (e) of this section, as to the name of a drug, the requirements of subsec. (e) should prevail.

Subsec. (*l*). Pub. L. 87-781, § 105(c), substituted "bacitracin, or any other antibiotic drug" for "or bacitracin."

Subsec. (n). Pub. L. 87-781, § 131(a), added subsec. (n).

Subsec. (o). Pub. L. 87-781, § 305, added subsec. (o).

1960—Subsec. (m). Pub. L. 86-618 added subsec. (m).

1953—Subsec. (*l*). Act Aug. 5, 1953, substituted "chlortetracycline" for "aureomycin".

1949—Subsec. (*l*). Act July 13, 1949, inserted ", aureomycin, chloramphenicol, or bacitracin" following "streptomycin".

1947—Subsec. (*l*). Act Mar. 10, 1947, inserted "or streptomycin" following "penicillin".

1945—Subsec. (*l*). Act July 6, 1945, added subsec. (*l*).

1941—Subsec. (k). Act Dec. 22, 1941, added subsec. (k).

1939—Subsec. (d). Act June 29, 1939, substituted "name, and quality or proportion" for "name, quantity, and percentage".

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91-601 effective Dec. 30, 1970, and regulations establishing special packaging standards effective no sooner than 180 days or later than one year from date regulations are final, or an earlier date published in Federal Register, see section 9 of Pub. L. 91-601, set out as an Effective Date note under section 1471 of Title 15, Commerce and Trade.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment of subsec. (*l*) of this section by Pub. L. 90-399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90-399, set out as an Effective Date note under section 360b of this title.

EFFECTIVE DATE OF 1962 AMENDMENT

Section 112(c) of Pub. L. 87-781 provided that: "This section [amending subsecs. (e) and (g) of this section] shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted [Oct. 1962]."

Section 131(b) of Pub. L. 87-781 provided that: "No drug which was being commercially distributed prior to the date of enactment of this Act [Oct. 10, 1962] shall be deemed to be misbranded under paragraph (n) of section 502 of the Federal Food, Drug, and Cosmetic Act [subsec. (n) of this section], as added by this section, until the earlier of the following dates: (1) the first day of the seventh month following the month in which this Act is enacted; or (2) the effective date of regulations first issued under clause (3) of such paragraph (n) in accordance with the procedure specified in section 701(e) of the Federal Food, Drug, and Cosmetic Act [section 371(e) of this title]."

Amendment by Pub. L. 87-781 effective on the first day of the seventh calendar month following Oct. 1962, see section 107 of Pub. L. 87-781, set out as an Effective Date of 1962 Amendment note under section 321 of this title.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective, subject to the provisions of section 203 of Pub. L. 86-618, on July 12, 1960, see section 202 of Pub. L. 86-618, set out as an Effective Date of 1960 Amendment note under section 376 of this title.

EFFECTIVE DATE; POSTPONEMENT

Subsecs. (b), (d) to (h) of this section effective Jan. 1, 1940 and such subsections effective July 1, 1940 as provided by regulations for certain lithographed labeling and containers bearing certain labeling, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date: Postponement in Certain Cases note under section 301 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

COUNTERFEITING OF DRUGS; CONGRESSIONAL FINDINGS AND DECLARATION OF POLICY

Section 9(a) of Pub. L. 89-74, July 15, 1965, 79 Stat. 234, provided that: "The Congress finds and declares that there is a substantial traffic in counterfeit drugs simulating the brand or other identifying mark or device of the manufacturer of the genuine article; that such traffic poses a serious hazard to the health of innocent consumers of such drugs because of the lack of proper qualifications, facilities, and manufacturing controls on the part of the counterfeiter, whose operations are clandestine; that, while such drugs are deemed misbranded within the meaning of section 502(i) of the Federal Food, Drug, and Cosmetic Act [subsec. (i) of this section], the controls for the suppression of the traffic in such drugs are inadequate because of the difficulty of determining the place of interstate origin of such drugs and, if that place is discovered, the fact that the implements for counterfeiting are not subject to seizure, and that these factors require enactment of additional controls with respect to such drugs without regard to their interstate or intrastate origins."

Provisions as effective Feb. 1, 1966, see section 11 of Pub. L. 89-74, set out as an Effective Date of 1965 Amendment note under section 321 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 333, 334, 353, 357, 360, 360b, 360c, 360j, 371, 802 of this title.

SECTION REFERRED TO IN D.C. CODE

This section is referred to in sections 33-702, 33-801 of the District of Columbia Code.

§ 353. Exemptions in case of drugs and devices

(a) Regulations for goods to be processed, labeled, or repacked elsewhere

The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(1) A drug intended for use by man which—

(A) is a habit-forming drug to which section 352(d) of this title applies; or

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to

its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except subsections (a), (i)(2) and (3), (k), and (*l*) of said section, and the packaging requirements of subsections (g), (h), and (p) of said section, if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to sections 352(d) and 355 of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law prohibits dispensing without prescription". A drug to which paragraph (1) of this subsection does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

(5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in sections 4721, 6001, and 6151 of title 26, or to marihuana as defined in section 4761 of title 26.

(June 25, 1938, ch. 675, § 503, 52 Stat. 1051; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; Oct. 26, 1951, ch. 578, § 1, 65 Stat. 648; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Oct. 10, 1962, Pub. L. 87-781, title I, § 104(e)(2), 76 Stat. 785; Dec. 30, 1970, Pub. L. 91-601, § 7(e), 84 Stat. 1673.)

CODIFICATION

"Sections 4721, 6001, and 6151 of title 26" and "section 4761 of title 26" were substituted for "section 3220 of the Internal Revenue Code (26 U.S.C. 3220)" and "section 3238(b) of the Internal Revenue Code (26 U.S.C. 3238(b))", respectively, in subsec. (b)(5), on authority of section 7852(b) of Title 26, Internal Revenue Code.

AMENDMENTS

1970—Subsec. (b)(2). Pub. L. 91-601 included exemption from packaging requirements of subsec. (p) of section 352 of this title.

1962—Subsec. (b)(1)(C). Pub. L. 87-781 substituted "approved" for "effective".

1951—Subsec. (b). Act Oct. 26, 1951, amended section generally to protect the public from abuses in the sale of potent prescription drugs, and to relieve retail pharmacists and the public from unnecessary restrictions on the dispensation of drugs that are safe to use without supervision of a doctor.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91-601 effective Dec. 30, 1970, and regulations establishing special packaging standards effective no sooner than 180 days or later than one year from date regulations are final, or an earlier date published in Federal Register, see section 9 of Pub. L. 91-601, set out as an Effective Date note under section 1471 of Title 15, Commerce and Trade.

EFFECTIVE DATE OF 1962 AMENDMENT; EXCEPTIONS

Amendment by Pub. L. 87-781 effective on Oct. 10, 1962, see section 107 of Pub. L. 87-781, set out as an Effective Date of 1962 Amendment note under section 321 of this title.

EFFECTIVE DATE OF 1951 AMENDMENT

Section 3 of act Oct. 26, 1951, provided that the amendment of this section should take effect six months after Oct. 26, 1951.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 333, 360, 825, 829, 885 of this title; title 15 section 1459.

SECTION REFERRED TO IN D.C. CODE

This section is referred to in section 33-702 of the District of Columbia Code.

§ 354. Repealed. Pub. L. 86-618, title I, § 103(a)(2), July 12, 1960, 74 Stat. 398

Section, act June 25, 1938, ch. 675, § 504, 52 Stat. 1052, required the Secretary to promulgate regulations for the listing of coal-tar colors, and is covered by section 376 of this title.

EFFECTIVE DATE OF REPEAL

Repeal of section effective, subject to the provisions of section 203 of Pub. L. 86-618, on July 12, 1960, see section 202 of Pub. L. 86-618, set out as an Effective Date of 1960 Amendment note under section 376 of this title.

§ 355. New drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

(b) Filing application; contents

Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

Within one hundred and eighty days after the filing of an application under this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies, or

(2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he

may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (j) of this section or to comply with the notice requirements of section 360(j)(2) of this title, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

(f) Revocation of order refusing, withdrawing or suspending approval of application

Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) of this section refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Service of orders

Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) Appeal from order

An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals or the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary

The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investi-

gator, or to clinics, for administration to human beings; and

(3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b) of this section.

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

(j) Records and reports; required information; regulations and orders; access to records

(1) In the case of any drug for which an approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section: *Provided, however,* That regulations and orders issued under this subsection and under subsection (i) of this section shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(June 25, 1938, ch. 675, § 505, 52 Stat. 1052; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; June 25, 1948, ch. 646, § 32(b), 62 Stat. 991; May 24, 1949, ch. 139, § 127, 63 Stat. 107; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; June 11, 1960, Pub. L. 86-507, § 1(18), 74 Stat. 201; Oct. 10, 1962, Pub. L. 87-781, title I, §§ 102(b)-(d), 103(a), (b), 104(a)-(d)(2), 76 Stat. 781-783, 784, 785; Aug. 16, 1972, Pub. L. 92-387, § 4(d), 86 Stat. 562.)

AMENDMENTS

1972—Subsec. (e). Pub. L. 92-387 inserted "or to comply with the notice requirements of section 360(j)(2) of this title" in clause (1) of the second sentence relating to the maintenance of records.

1962—Subsec. (a). Pub. L. 87-781, § 104(a), inserted "an approval of" preceding "an application".

Subsec. (b). Pub. L. 87-781, § 102(b), inserted "and whether such drug is effective in use" following "is safe for use".

Subsec. (c). Pub. L. 87-781, § 104(b), substituted provisions requiring the Secretary, within 180 days after filing an application, or such additional period as the Secretary and the applicant agree upon, to either approve the application, if meeting the requirements of subsec. (d) of this section, or give notice of opportunity for hearing on question of whether such application is approvable, and providing that if applicant requests hearing in writing within 30 days, the hearing shall begin within 90 days after expiration of said 30 days, unless the Secretary and applicant agree otherwise, that such hearing shall be expedited, and that the Secretary's order shall be issued within 90 days after date for filing final briefs, for provisions which had an application become effective on the sixtieth day after filing thereof unless prior thereto the Secretary postponed the date by written notice to such time, but not more than 180 days after filing, as the Secretary deemed necessary to study and investigate the application.

Subsec. (d). Pub. L. 87-781, § 102(c), inserted references to subsec. (c), added clauses (5) and (6), provided that if after notice and opportunity for hearing, the Secretary finds that clauses (1) to (6) do not apply, he shall approve the application, and defined "substantial evidence" as used in this subsection and subsec. (e) of this section.

Subsec. (e). Pub. L. 87-781, § 102(d), amended subsection generally, and among other changes, directed the Secretary to withdraw approval of an application if by tests, other scientific data or experience, or new evidence of clinical experience not contained in the application or available at the time of its approval, the drug is shown to be unsafe, or on the basis of new information, there is shown a lack of substantial evidence that the drug has the effect it is represented to have, and provided that if the Secretary, or acting Secretary, finds there is an imminent hazard to the public health, he may suspend approval immediately, notify the applicant, and give him opportunity for an expedited hearing, that the Secretary may withdraw approval if the applicant fails to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain records and make reports, or has refused access to, or copying or verification of such records, or if the Secretary finds on new evidence that the methods, facilities and controls in the manufacturing, processing, and packing are inadequate to assure and preserve the drugs' identity, strength, quality and purity, and were not made adequate within a reasonable time after receipt of written notice thereof, or finds on new evidence, that the labeling is false or misleading and was not corrected within a reasonable time after receipt of written notice thereof.

Subsec. (f). Pub. L. 87-781, § 104(c), substituted provisions requiring the Secretary to revoke any previous order under subsecs. (d) or (e) of this section refusing, withdrawing, or suspending approval of an application and to approve such application or reinstate such approval, for provisions which required him to revoke an order refusing effectiveness to an application.

Subsec. (h). Pub. L. 87-781, § 104(d)(1), (2), inserted "as provided in section 2112 of title 28", and "except

that until the filing of the record the Secretary may modify or set aside his order", substituted "or withdrawing approval of an application under this section" for "to permit the application to become effective, or suspending the effectiveness of the application", "United States court of appeals for the circuit" for "district court of the United States within any district", "Court of Appeals for the District of Columbia Circuit" for "District Court for the District of Columbia", "transmitted by the clerk of the court to" for "served upon", and "by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28" for "as provided in sections 225, 346, and 347 of title 28, as amended, and in section 7, as amended, of the Act entitled 'An Act to establish a Court of Appeals for the District of Columbia', approved February 9, 1893", and eliminated "upon" preceding "any officer designated", "a transcript of" preceding "the record" and "and decree" preceding "of the court affirming".

Subsec. (i). Pub. L. 87-781, § 103(b), inserted "the foregoing subsections of" following "operation of", and "and effectiveness" following "safety", and provided that the regulations may condition exemptions upon the submission of reports of preclinical tests to justify the proposed clinical testing, upon the obtaining by the manufacturer or sponsor of the investigation of a new drug of a signed agreement from each of the investigators that patients to whom the drug is administered will be under his supervision or under investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings, or upon the establishment and maintenance of records and reports of data obtained by the investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug, and provided that the regulations shall condition an exemption upon the manufacturer or sponsor of the investigation requiring that experts using such drugs certify that they will inform humans to whom such drugs or any controls connected therewith are administered, or their representatives, and will obtain the consent of such people where feasible and not contrary to the best interests of such people, and that reports on the investigational use of drugs are not required to be submitted directly to the Secretary.

Subsec. (j). Pub. L. 87-781, § 103(a), added subsec. (j).

1960—Subsec. (g). Pub. L. 86-507 inserted "or by certified mail" following "registered mail".

CHANGE OF NAME

Act June 25, 1948, eff. Sept. 1, 1948, as amended by act May 24, 1949, substituted "United States District Court for the District of Columbia" for "District Court of the United States for the District of Columbia."

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92-387 effective on the first day of the sixth month beginning after Aug. 16, 1972, see section 5 of Pub. L. 92-387, set out as an Effective Date of 1972 Amendment note under section 360 of this title.

EFFECTIVE DATE OF 1962 AMENDMENT; EXCEPTIONS

Amendment by Pub. L. 87-781 effective on the first day of the seventh calendar month following Oct. 1962, see section 107 of Pub. L. 87-781, set out as an Effective Date of 1962 Amendment note under section 321 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

APPEALS TAKEN PRIOR TO OCTOBER 10, 1962

Section 104(d)(3) of Pub. L. 87-781 made amendments to subsec. (h) of this section inapplicable to any appeal taken prior to Oct. 10, 1962.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 333, 334, 353, 357, 360, 360b, 360j, 374, 381, 827 of this title.

§ 356. Certification of drugs containing insulin

(a) Standards for certification

The Secretary of Health, Education, and Welfare, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of insulin. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Secretary prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Secretary, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof.

(b) Regulations

Regulations providing for such certification shall contain such provisions as are necessary to carry out the purposes of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service. Such regulations shall prescribe no standard of identity or of strength, quality, or purity for any drug different from the standard of identity, strength, quality, or purity set forth for such drug in an official compendium.

(c) Tests or methods of assay; revision

Such regulations, insofar as they prescribe tests or methods of assay to determine strength, quality, or purity of any drug, different from the tests or methods of assay set forth for such drug in an official compendium, shall be prescribed, after notice and opportunity for revision of such compendium, in the manner provided in the second sentence of section 351(b) of this title. The provisions of subsections (e), (f), and (g) of section 371 of this title shall be applicable to such portion of any regulation as prescribes any such different test or method, but shall not be applicable to any other portion of any such regulation.

(June 25, 1938, ch. 675, § 506, as added Dec. 22, 1941, ch. 613, § 3, 55 Stat. 851, and amended 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

REGULATIONS

Section 4 of Act Dec. 22, 1941, directed that regulations initially prescribed under this section were to be promulgated and made effective within forty-five days after Dec. 22, 1941.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352, 360 of this title; title 15 section 1459.

§ 357. Certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug

(a) Regulations prescribed by Secretary; release prior to certification; "antibiotic drug" defined

The Secretary of Health, Education, and Welfare, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs (except drugs for use in animals other than man) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Secretary prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Secretary, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof. For purposes of this section and of section 352(*l*) of this title, the term "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance).

(b) Provisions of regulations

Regulations providing for such certifications shall contain such provisions as are necessary to carry out the purposes of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service. Such regulations shall prescribe only such tests and methods of assay as will provide for certification or rejection within the shortest time consistent with the purposes of this section.

(c) Exemption of drugs not involving safety and efficacy of use; considerations; certification after exemption; labeling and advertising claims

Whenever in the judgment of the Secretary, the requirements of this section and of section 352(*l*) of this title with respect to any drug or class of drugs are not necessary to insure safety and efficacy of use, the Secretary shall promulgate regulations exempting such drug or class of drugs from such requirements. In deciding whether an antibiotic drug, or class of antibiotic drugs, is to be exempted from the requirement of certification the Secretary shall give consideration, among other relevant factors, to—

(1) whether such drug or class of drugs is manufactured by a person who has, or hereafter shall have, produced fifty consecutive batches of such drug or class of drugs in compliance with the regulations for the certification thereof within a period of not more than eighteen calendar months, upon the application by such person to the Secretary; or

(2) whether such drug or class of drugs is manufactured by any person who has otherwise demonstrated such consistency in the production of such drug or class of drugs, in compliance with the regulations for the certification thereof, as in the judgment of the Secretary is adequate to insure the safety and efficacy of use thereof.

When an antibiotic drug or a drug manufacturer has been exempted from the requirement of certification, the manufacturer may still obtain certification of a batch or batches of that drug if he applies for and meets the requirements for certification. Nothing in this chapter shall be deemed to prevent a manufacturer or distributor of an antibiotic drug from making a truthful statement in labeling or advertising of the product as to whether it has been certified or exempted from the requirement of certification.

(d) Exemption of drugs stored, processed, and labeled at plants other than manufacturer's, used in manufacture of other drugs or for investigational purposes; discretionary and mandatory conditions; direct reports to Secretary

The Secretary shall promulgate regulations exempting from any requirement of this section and of section 352(*l*) of this title, (1) drugs which are to be stored, processed, labeled, or repacked at establishments other than those where manufactured, on condition that such drugs comply with all such requirements upon removal from such establishments; (2) drugs which conform to applicable standards of identity, strength, quality, and purity prescribed by these regulations and are intended for use in manufacturing other drugs; and (3) drugs which are intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning the exemption under clause (3) of this subsection upon—

(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, or preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

(3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application for certification or release pursuant to subsection (a) of this section.

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

(e) Exempted new drugs subject to section 355 of this title; request for certification of exempted drug; determination of compliance with sections 351(b) and 352(g) of this title

No drug which is subject to this section shall be deemed to be subject to any provision of section 355 of this title except a new drug exempted from the requirements of this section and of section 352(*l*) of this title pursuant to regulations promulgated by the Secretary: *Provided,* That, for purposes of section 355 of this title, the initial request for certification, as thereafter duly amended, pursuant to this section, of a new drug so exempted shall be considered a part of the application filed pursuant to section 355(b) of this title with respect to the person filing such request and to such drug of the date of the exemption. Compliance of any drug subject to section 352(*l*) of this title or this section with sections 351(b) and 352(g) of this title shall be determined by the application of the standards of strength, quality, and purity, the tests and methods of assay, and the requirements of packaging and labeling, respectively, prescribed by regulations promulgated under this section.

(f) Filing of petitions; contents; notice; answer; public hearing; orders

Any interested person may file with the Secretary a petition proposing the issuance, amendment, or repeal of any regulation contemplated by this section. The petition shall set forth the proposal in general terms and shall state reasonable grounds therefor. The Secretary shall give public notice of the proposal and an opportunity for all interested persons to present their views thereon, orally or in writing, and as soon as practicable thereafter shall make public his action upon such proposal. At any time prior to the thirtieth day after such action is made public any interested person may file objections to such action, specifying with particularity the changes desired, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall thereupon, after due notice, hold such public hearing. As soon as practicable after completion of the hearing, the Secretary shall by order make public his action on such objections. The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. The order shall be subject to the provisions of section 371(f) and (g) of this title.

(g) Records and reports; professional ethics and interests of patients; examination of data; access to records

(1) Every person engaged in manufacturing, compounding, or processing any drug within the purview of this section with respect to which a certificate or release has been issued pursuant to this section shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such person with respect to such drug, as the Secretary may be general regulation, or by order with respect to such certification or release, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to make, or to facilitate, a determination as to whether such certification or release should be rescinded or whether any regulation issued under this section should be amended or repealed: *Provided, however,* That regulations and orders issued under this subsection and under clause (3) of subsection (d) of this section shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person having charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(h) Issuance of regulations; conditions; amendment or repeal of regulations; effective date; procedure; lack of substantial evidence

In the case of a drug for which, on the day immediately preceding May 1, 1963, a prior approval of an application under section 355 of this title had not been withdrawn under section 355(e) of this title, the initial issuance of regulations providing for certification or exemption of such drug under this section shall, with respect to the conditions of use prescribed, recommended, or suggested in the labeling covered by such application, not be conditioned upon an affirmative finding of the efficacy of such drug. Any subsequent amendment or repeal of such regulations so as no longer to provide for such certification or exemption on the ground of a lack of efficacy of such drug for use under such conditions of use may be effected only on or after May 1, 1963, which would be applicable to such drug under such conditions of use if such drug were subject to section 355(e) of this title, and then only if (1) such amendment or repeal is made in accordance with the procedure specified in subsection (f) of this section (except that such amendment or repeal may be initiated either by a proposal of the Secretary or by a petition of any interested person) and (2) the Secretary finds, on the basis of new information with respect to such drug evaluated together with the information before him when the application under section 355 of this title became effective or was approved, that there is a lack of substantial evidence (as defined in section 355(d) of this title) that the drug has the effect it purports or is represented to have under such conditions of use.

(June 25, 1938, ch. 675, § 507, as added July 6, 1945, ch. 281, § 3, 59 Stat. 463, and amended Mar. 10, 1947, ch. 16, § 3, 61 Stat. 12; July 13, 1949, ch. 305, § 2, 63 Stat. 409; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 5, 1953, ch. 334, § 2(a), (b), 67 Stat. 389; Oct. 10, 1962, Pub. L. 87-781, title I, §§ 105(a), (b), (d)-(f), 106(a), (b), 76 Stat. 785, 786, 787; July 13, 1968, Pub. L. 90-399, § 105(b), 82 Stat. 352.)

AMENDMENTS

1968—Subsec. (a). Pub. L. 90-399 inserted "(except drugs for use in animals other than man)" following "drugs" in the first sentence.

1962—Subsec. (a). Pub. L. 87-781, § 105(a), (b), inserted the definition of "antibiotic drug" and substituted "bacitracin, or any other antibiotic drug" for "or bacitracin".

Subsec. (c). Pub. L. 87-781, § 105(d), required the Secretary to consider, among other relevant factors, whether such drug or class of drugs is manufactured by anyone who has, or shall have, produced 50 consecutive batches in compliance with the regulations for certification, within a period of not more than 18 months, or whether it is manufactured by anyone who has otherwise demonstrated such consistency in production as the Secretary determines is adequate to insure the safety and efficacy thereof, and provided that an exempted manufacturer may still obtain certification of a batch or batches of a drug if he applies for and meets the requirements, and that nothing in this chapter shall be deemed to prevent a truthful statement in labeling or advertising of whether or not the product has been certified or exempted from the requirement of certification.

Subsec. (d). Pub. L. 87-781, § 106(b), provided that the regulations may condition the exemption under clause (3) of this subsection upon the submission of reports of preclinical tests to justify the proposed clinical testing, upon the obtaining by the manufacturer or sponsor of the investigation of a new drug of a signed agreement from each of the investigators that patients to whom the drug is administered will be under his supervision, or under investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings, or upon the establishment and maintenance of records and reports of data obtained by the investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug, and that the regulations shall condition an exemption upon the manufacturer or sponsor of the investigation requiring that experts using such drugs certify that they will inform humans to whom such drugs or any controls connected therewith are administered, or their representatives, and will obtain the consent of such people where feasible and not against the best interests of such people, and that reports on the investigational use of drugs are not required to be submitted directly to the Secretary.

Subsec. (e). Pub. L. 87-781, § 105(e), subjected new drugs, exempted from the requirements of this section and of section 352(*l*) of this title to section 355 of this title, and provided that for purposes of said section 355, the initial request for certification, as thereafter amended, pursuant to this section, shall be considered a part of the application filed pursuant to section 355(b) of this title with respect to the person filing, and to the drug in question as of the date of the exemption.

Subsec. (g). Pub. L. 87-781, § 106(a), added subsec. (g).

Subsec. (h). Pub. L. 87-781, § 105(f), added subsec. (h).

1953—Act Aug. 5, 1953, § 2(a), substituted "chlortetracycline" for "aureomycin" in catchline.

Subsec. (a). Act Aug. 5, 1953, § 2(b), substituted "chlortetracycline" for "aureomycin".

1949—Act July 13, 1949, § 2(a), added "aureomycin, chloramphenicol, or bacitracin" in catchline.

Subsec. (a). Act July 13, 1949, § 2(b), inserted ", aureomycin, chloramphenicol, or bacitracin" following "streptomycin".

1947—Act Mar. 10, 1947, inserted "or streptomycin" after "penicillin" in catchline.

Subsec. (a). Act Mar. 10, 1947, inserted "or streptomycin" following "penicillin" in first sentence.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment of subsec. (a) of this section by Pub. L. 90-399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90-399, set out as an Effective Date note under section 360b of this title.

EFFECTIVE DATE OF 1962 AMENDMENT; EXCEPTIONS

Amendment by Pub. L. 87-781 effective on the first day of the seventh calendar month following Oct. 1962, see section 107 of Pub. L. 87-781, set out as an Effective Date of 1962 Amendment note under section 321 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352, 360, 360b, 360j, 374 of this title.

§ 358. Authority to designate official names

(a) Necessity or desirability; use in official compendiums; infringement of trademarks

The Secretary may designate an official name for any drug or device if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Any official name designated under this section for any drug or device shall be the only official name of that drug or device used in any official compendium published after such name has been prescribed or for any other purpose of this chapter. In no event, however, shall the Secretary establish an official name so as to infringe a valid trademark.

(b) Review of names in official compendiums

Within a reasonable time after October 10, 1962, and at such other times as he may deem necessary, the Secretary shall cause a review to be made of the official names by which drugs are identified in the official United States Pharmacopoeia, the official Homoeopathic Pharmacopoeia of the United States, and the official National Formulary, and all supplements thereto, and at such times as he may deem necessary shall cause a review to be made of the official names by which devices are identified in any official compendium (and all supplements thereto) to determine whether revision of any of those names is necessary or desirable in the interest of usefulness and simplicity.

(c) Determinations of complexity, usefulness, multiplicity, or lack of name; designation by Secretary

Whenever he determines after any such review that (1) any such official name is unduly complex or is not useful for any other reason, (2) two or more official names have been applied to a single drug or device, or to two or more drugs which are identical in chemical structure and pharmacological action and which are substantially identical in strength, quality, and purity, or to two or more devices which are substantially equivalent in design and purpose or (3) no official name has been applied to a medically useful drug or device, he shall transmit in writing to the compiler of each official compendium in which that drug or drugs or device are identified and recognized his request for the recommendation of a single official name for such drug or drugs or device which will have usefulness and simplicity. Whenever such a single official name has not been recommended within one hundred and eighty days after such request, or the Secretary determines that any name so recommended is not useful for any reason, he shall designate a single official name for such drug or drugs or device. Whenever he determines that the name so recommended is useful, he shall designate that name as the official name of such drug or drugs or device. Such designation shall be made as a regulation upon public notice and in accordance with the procedure set forth in section 553 of title 5.

(d) Revised official names; compilation, publication, and public distribution of listings

After each such review, and at such other times as the Secretary may determine to be necessary or desirable, the Secretary shall cause to be compiled, published, and publicly distributed a list which shall list all revised official names of drugs or devices designated under this section and shall contain such descriptive and explanatory matter as the Secretary may determine to be required for the effective use of those names.

(e) Request by compiler of official compendium for designation of name

Upon a request in writing by any compiler of an official compendium that the Secretary exercise the authority granted to him under subsection (a) of this section, he shall upon public notice and in accordance with the procedure set forth in section 553 of title 5 designate the official name of the drug or device for which the request is made.

(June 25, 1938, ch. 675, § 508, as added Oct. 10, 1962, Pub. L. 87-781, title I, § 111(a), 76 Stat. 789, and amended May 28, 1976, Pub. L. 94-295, § 5(b), 90 Stat. 581.)

CODIFICATION

"Section 553 of title 5" was substituted for "section 4 of the Administrative Procedure Act (5 U.S.C. 1003)", in subsecs. (c) and (e), on authority of section 7(b) of Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 631, section 1 of which enacted Title 5, Government Organization and Employees.

AMENDMENTS

1976—Subsec. (a). Pub. L. 94-295 substituted "drug or device" for "drug" wherever appearing.

Subsec. (b). Pub. L. 94-295 substituted "National Formulary, and all supplements thereto, and at such times as he may deem necessary shall cause a review to be made of the official names by which devices are identified in any official compendium (and all supplements thereto)" for "National Formulary, and all supplements thereto,".

Subsec. (c)(2). Pub. L. 94-295 added "or device" following "single drug", and added "or to two or more devices which are substantially equivalent in design and purpose" following "purity,".

Subsec. (c)(3). Pub. L. 94-295 added "or device" following "useful drug" and following "drug or drugs" wherever appearing.

Subsec. (d). Pub. L. 94-295 added "or devices" following "drugs".

Subsec. (e). Pub. L. 94-295 substituted "drug or device" for "drug".

EFFECTIVE DATE

Section 111(b) of Pub. L. 87-781 provided that: "This section [adding this section] shall take effect on the date of its enactment [Oct. 10, 1962]."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 352 of this title.

SECTION REFERRED TO IN D.C. CODE

This section is referred to in section 33-801 of the District of Columbia Code.

§ 359. Nonapplicability of subchapter to cosmetics

This subchapter, as amended by the Drug Amendments of 1962, shall not apply to any cosmetic unless such cosmetic is also a drug or device or component thereof.

(June 25, 1938, ch. 675, § 509, as added Oct. 10, 1962, Pub. L. 87-781, title I, § 113, 76 Stat. 791.)

REFERENCES IN TEXT

This subchapter, as amended by the Drug Amendments of 1962, referred to in text, means the amend-

ment of this subchapter by Pub. L. 87-781 which added sections 358 to 360 of this title, amended sections 351 to 353, 355, and 357 of this title, and enacted provisions set out as notes under sections 352, 355, 358, and 360 of this title.

The Drug Amendments of 1962, referred to in text, is Pub. L. 87-781, Oct. 10, 1962, 76 Stat. 780. For complete classification of this Act to the Code, see Tables volume.

§ 360. Registration of producers of drugs or devices

(a) Definitions

As used in this section—

(1) the term "manufacture, preparation, propagation, compounding, or processing" shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user; and

(2) the term "name" shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

(b) Annual registration

On or before December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices shall register with the Secretary his name, places of business, and all such establishments.

(c) New producers

Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices in any establishment which he owns or operates in any State shall immediately register with the Secretary his name, place of business, and such establishment.

(d) Additional establishments

Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Secretary any additional establishment which he owns or operates in any State and in which he begins the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices.

(e) Registration number; uniform system for identification of devices intended for human use

The Secretary may assign a registration number to any person or any establishment registered in accordance with this section. The Secretary may also assign a listing number to each drug or class of drugs listed under subsection (j) of this section. Any number assigned pursuant to the preceding sentence shall be the same as that assigned pursuant to the National Drug Code. The Secretary may by regulation prescribe a uniform system for the identification of devices intended for human use and may require that persons who are required to list such devices pursuant to subsection (j) of this section shall list such devices in accordance with such system.

(f) Availability of registrations for inspection

The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this section; except that any list submitted pursuant to paragraph (3) of subsection (j) of this section and the information accompanying any list or notice filed under paragraph (1) or (2) of that subsection shall be exempt from such inspection unless the Secretary finds that such an exemption would be inconsistent with protection of the public health.

(g) Exclusions from application of section

The foregoing subsections of this section shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(2) practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in research, teaching, or chemical analysis and not for sale;

(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

(h) Inspection of premises

Every establishment in any State registered with the Secretary pursuant to this section shall be subject to inspection pursuant to section 374 of this title and every such establishment engaged in the manufacture, propagation, compounding, or processing of a drug or drugs or of a device or devices classified in class II or III shall be so inspected by one or more officers or employees duly designated by the Secretary at least once in the two-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive two-year period thereafter.

(i) Foreign establishments

Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs, or a device or devices, shall be permitted to register under this section pursuant to regulations promulgated by the Secretary. Such regulations shall require such establishment to provide the information required by subsection (j) of this section and shall require such establishment to provide the information required by subsection (j) of this section in the case of a device or devices and shall in-

clude provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether drugs or devices manufactured, prepared, propagated, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 381(a) of this title.

(j) Filing of lists of drugs and devices manufactured, prepared, propagated and compounded by registrants; statements; accompanying disclosures

(1) Every person who registers with the Secretary under subsection (b), (c), or (d) of this section shall, at the time of registration under any such subsection, file with the Secretary a list of all drugs and a list of all devices and a brief statement of the basis for believing that each device included in the list is a device rather than a drug (with each drug and device in each list listed by its established name (as defined in section 352(e) of this title) and by any proprietary name) which are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution and which he has not included in any list of drugs or devices filed by him with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

(A) in the case of a drug contained in the applicable list and subject to sections 355, 356, 357, or 360b of this title, or a device intended for human use contained in the applicable list with respect to which a performance standard has been established under section 360d of this title or which is subject to section 360e of this title, a reference to the authority for the marketing of such drug or device and a copy of all labeling for such drug or device;

(B) in the case of any other drug or device contained in an applicable list—

(i) which drug is subject to section 353(b)(1) of this title, or which device is a restricted device, a copy of all labeling for such drug or device, a representative sampling of advertisements for such drug or device, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product or device, or

(ii) which drug is not subject to section 353(b)(1) of this title or which device is not a restricted device, the label and package insert for such drug or device and a representative sampling of any other labeling for such drug or device;

(C) in the case of any drug contained in an applicable list which is described in subparagraph (B), a quantitative listing of its active ingredient or ingredients, except that with respect to a particular drug product the Secretary may require the submission of a quantitative listing of all ingredients if he finds that such submission is necessary to carry out the purposes of this chapter; and

(D) if the registrant filing a list has determined that a particular drug product or device contained in such list is not subject to section 355, 356, 357, or 360b of this title, or the particular device contained in such list is not subject to a performance standard established under section 360d of this title or to section 360e of this title or is not a restricted device a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular drug product or device.

(2) Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following information:

(A) A list of each drug or device introduced by the registrant for commercial distribution which has not been included in any list previously filed by him with the Secretary under this subparagraph or paragraph (1) of this subsection. A list under this subparagraph shall list a drug or device by its established name (as defined in section 352(e) of this title), and by any proprietary name it may have and shall be accompanied by the other information required by paragraph (1).

(B) If since the date the registrant last made a report under this paragraph (or if he has not made a report under this paragraph, since February 1, 1973) he has discontinued the manufacture, preparation, propagation, compounding, or processing for commercial distribution of a drug or device included in a list filed by him under subparagraph (A) or paragraph (1); notice of such discontinuance, the date of such discontinuance, and the identity (by established name (as defined in section 352(e) of this title) and by any proprietary name) of such drug or device.

(C) If since the date the registrant reported pursuant to subparagraph (B) a notice of discontinuance he has resumed the manufacture, preparation, propagation, compounding, or processing for commercial distribution of the drug or device with respect to which such notice of discontinuance was reported; notice of such resumption, the date of such resumption, the identity of such drug or device (each by established name (as defined in section 352(e) of this title) and by any proprietary name), and the other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary pursuant to this subparagraph.

(D) Any material change in any information previously submitted pursuant to this paragraph or paragraph (1).

(3) The Secretary may also require each registrant under this section to submit a list of each drug product which (A) the registrant is manufacturing, preparing, propagating, compounding, or processing for commercial distribution, and (B) contains a particular ingredient. The Secretary may not require the submission of such a list unless he has made a finding that the submission of such a list is necessary to carry out the purposes of this chapter.

(k) Report preceding introduction of devices into interstate commerce

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe)—

(1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 360d or 360e of this title which are applicable to the device.

(June 25, 1938, ch. 675, § 510, as added Oct. 10, 1962, Pub. L. 87-781, title III, § 302, 76 Stat. 794, and amended July 15, 1965, Pub. L. 89-74, § 4, 79 Stat. 231; Oct. 27, 1970, Pub. L. 91-513, title II, § 701(e), 84 Stat. 1282; Aug. 16, 1972, Pub. L. 92-387, §§ 3, 4(a)-(c), 86 Stat. 560-562; May 28, 1976, Pub. L. 94-295, § 4(a), 90 Stat. 579.)

AMENDMENTS

1976—Subsec. (a)(1). Pub. L. 94-295, § 4(a)(2), substituted "drug package or device package" for "drug package", "distribution of the drug or device" for "distribution of the drug", and "ultimate consumer or user" for "ultimate consumer".

Subsecs. (b) to (d). Pub. L. 94-295, § 4(a)(3), added "or a device or devices" after "drug or drugs" in subsecs. (b), (c), and (d).

Subsec. (e). Pub. L. 94-295, § 4(a)(4), authorized the Secretary to prescribe by regulation a uniform system for the identification of devices intended for human use and authorized him, in addition, to require that persons who are required to list devices pursuant to subsec. (j) also list such devices in accordance with the system.

Subsec. (g). Pub. L. 94-295, § 4(a)(5), substituted "drugs or devices" for "drugs" in pars. (1), (2), and (3).

Subsec. (h). Pub. L. 94-295, § 4(a)(6), added reference to establishments engaged in the manufacture, propagation, compounding, or processing of a drug or drugs or of a device or devices classified in class II or III.

Subsec. (i). Pub. L. 94-295, § 4(a)(7), added references to devices and added requirement that regulations require establishments to provide the information required by subsection (j) of this section in the case of a device or devices.

Subsec. (j)(1). Pub. L. 94-295, § 4(a)(8)(A), in the introductory provisions substituted "a list of all drugs and a list of all devices and a brief statement of the basis for believing that each device included in the list is a device rather than a drug (with each drug and device in each list listed by its established name" for "a list of all drugs (by established name" and "drugs or devices filed" for "drugs filed".

Subsec. (j)(1)(A). Pub. L. 94-295, § 4(a)(8)(B), substituted "the applicable list" for "such list", added "or a device intended for human use contained in the applicable list with respect to which a performance standard has been established under section 360d of this title or which is subject to section 360e of this title," following "360b of this title,", and substituted "such drug or device" for "such drug" wherever appearing.

Subsec. (j)(1)(B). Pub. L. 94-295, § 4(a)(8)(C), in the introductory provisions substituted "drug or device contained in an applicable list" for "drug contained in such list".

Subsec. (j)(1)(B)(i). Pub. L. 94-295, § 4(a)(8)(D), substituted "which drug is subject to section 353(b)(1) of this title, or which device is a restricted device, a copy of all labeling for such drug or device, a representative sampling of advertisements for such drug or device, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product or device, or" for "which is subject to section 353(b)(1) of this title, a copy of all labeling for such drug, a representative sampling of advertisements for such drug, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product, or".

Subsec. (j)(1)(B)(ii). Pub. L. 94-295, § 4(a)(8)(E), substituted "which drug is not subject to section 353(b)(1) of this title or which device is not a restricted device, the label and package insert for such drug or device and a representative sampling of any other labeling for such drug or device" for "which is not subject to section 353(b)(1) of this title, the label and package insert for such drug and a representative sampling of any other labeling for such drug".

Subsec. (j)(1)(C). Pub. L. 94-295, § 4(a)(8)(F), substituted "an applicable list" for "such list".

Subsec. (j)(1)(D). Pub. L. 94-295, § 4(a)(8)(G), substituted "a list" for "the list", added "or the particular device contained in such list is not subject to a performance standard established under section 360d of this title or to section 360e of this title or is not a restricted device" following "or 360b of this title,", and substituted "particular drug product or device" for "particular drug product" wherever appearing.

Subsec. (j)(2). Pub. L. 94-295, § 4(a)(8)(H), substituted "drug or "device" for "drug" in subpars. (A), (B), and (C), and substituted "(each by established name" for "(by established name" in subpar. (C).

Subsec. (k). Pub. L. 94-295, § 4(a)(9), added subsec. (k).

1972—Subsec. (e). Pub. L. 92-387, § 4(a), added provision that the Secretary may assign a listing number to each drug or class of drugs listed under subsec. (j).

Subsec. (f). Pub. L. 92-387, § 4(b), added exception that the list submitted under subsec. (j)(3) and information submitted under subsec. (j)(1), (2) shall be exempt from inspection unless the Secretary determines otherwise.

Subsec. (i). Pub. L. 92-387, § 4(c), added provision that the regulations shall require such establishment to provide the information required by subsec. (j).

Subsec. (j). Pub. L. 92-387, § 3, added subsec. (j).

1970—Subsec. (a). Pub. L. 91-513 struck out provisions defining the wholesaling, jobbing, or distributing of depressant or stimulant drugs.

Subsec. (b). Pub. L. 91-513 struck out provisions covering establishments engaged in the wholesaling, jobbing, or distributing of depressant or stimulant drugs and the inclusion of the fact of such activity in the annual registration.

Subsec. (c). Pub. L. 91-513 struck out provisions covering new registrations of persons first engaging in the wholesaling, jobbing, or distributing of depressant or stimulant drugs and the inclusion of the fact of such activity in the registration.

Subsec. (d). Pub. L. 91-513 struck out number designation "(1)" preceding the first sentence, struck out portion of such redesignated provisions covering the wholesaling, jobbing, or distributing of depressant or stimulant drugs, and struck out par. (2) covering the filing of supplemental registration whenever a person not previously engaged or involved with depressant or stimulant drugs goes into the manufacturing, preparation, or processing thereof.

1965—Pub. L. 89-74, § 4(e), included certain wholesalers in the catchline.

Subsec. (a). Pub. L. 89-74, § 4(a), added par. (2) and redesignated former par. (2) as (3).

Subsecs. (b), (c). Pub. L. 89-74, § 4(b), (c), inserted "or in the wholesaling, jobbing, or distributing of any depressant or stimulant drug" following "drug or drugs" and added requirement that establishment indicate activity in depressant or stimulant drugs at time of registration.

Subsec. (d). Pub. L. 89-74 § 4(d), designated existing provisions as par. (1), added thereto "or the wholesaling, jobbing, or distributing of any depressant or stimulant drug." and the requirement that the additional establishment indicate activity in depressant or stimulant drugs at time of registration, and added par. (2).

EFFECTIVE DATE OF 1972 AMENDMENT

Section 5 of Pub. L. 92-387 provided that: "The amendments made by this Act [amending sections 331, 335, and 360 of this title and enacting provisions set out as notes under section 360 of this title] shall take effect on the first day of the sixth month beginning after the date of enactment of this Act [Aug. 16, 1972]."

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91-513 effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91-513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89-74 effective Feb. 1, 1966, subject to registration with Secretary of names, places of business, establishments, and other prescribed information prior to Feb. 1, 1966, see section 11 of Pub. L. 89-74, set out as an Effective Date of 1965 Amendment note under section 321 of this title.

SAVINGS PROVISIONS

Amendment by Pub. L. 91-513 not to affect or abate any prosecutions for any violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now the Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91-513, set out as a Savings Provisions note under section 321 of this title.

CONGRESSIONAL DECLARATION OF NEED FOR REGISTRATION AND INSPECTION OF DRUG ESTABLISHMENTS

Section 301 of Pub. L. 87-781 provided that: "The Congress hereby finds and declares that in order to make regulation of interstate commerce in drugs effective, it is necessary to provide for registration and inspection of all establishments in which drugs are manufactured, prepared, propagated, compounded, or processed; that the products of all such establishments are likely to enter the channels of interstate commerce and directly affect such commerce; and that the regulation of interstate commerce in drugs without provision for registration and inspection of establishments that may be engaged only in intrastate commerce in such drugs would discriminate against and depress interstate commerce in such drugs, and adversely burden, obstruct, and affect such interstate commerce."

DECLARATION OF POLICY OF DRUG LISTING ACT OF 1972

Section 2 of Pub. L. 92-387 provided that: "The Federal Government which is responsible for regulating drugs has no ready means of determining what drugs are actually being manufactured or packed by establishments registered under the Federal Food, Drug, and Cosmetic Act [this chapter] except by periodic inspection of such registered establishments. Knowledge of which particular drugs are being manufactured or packed by each registered establishment would substantially assist in the enforcement of Federal laws requiring that such drugs be pure, safe, effective, and properly labeled. Information on the discontinuance of a particular drug could serve to alleviate the burden of reviewing and implementing enforcement actions against drugs which, although commercially discontinued, remain active for regulatory purposes. Information on the type and number of different drugs being manufactured or packed by drug establishments could permit more effective and timely regulation by the agencies of the Federal Government responsible for regulating drugs, including identification of which drugs in interstate commerce are subject to section 505 or 507 [section 355 or 357 of this title], or to other provisions of the Federal Food, Drug, and Cosmetic Act."

REGISTRATION OF CERTAIN PERSONS OWNING OR OPERATING DRUG ESTABLISHMENTS PRIOR TO OCT. 10, 1962

Section 303 of Pub. L. 87-781 provided that any person who, on the day immediately preceding Oct. 10, 1962, owned or operated an establishment which manufactured or processed drugs, registered before the first day of the seventh month following October, 1962, would be deemed to be registered in accordance with subsec. (b) of this section for the calendar year 1962 and if registered within this period and effected in 1963, be deemed in compliance for that calendar year.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352, 355, 360c, 360e, 360j, 381 of this title.

§ 360a. Repealed. Pub. L. 91-513, title II, § 701(a), Oct. 27, 1970, 84 Stat. 1281

Section, act June 25, 1938, ch. 675, § 511, as added July 15, 1965, Pub. L. 89-74, § 3(b), 79 Stat. 227, and amended Oct. 24, 1968, Pub. L. 90-639, § 2(a), 82 Stat. 1361, regulated the manufacture, compounding, and processing of depressant and stimulant drugs and their sale, delivery, disposal, possession, and record-keeping activities connected therewith. See section 801 et seq. of this title.

EFFECTIVE DATE OF REPEAL

Repeal by Pub. L. 91-513 effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91-513, set out as an Effective Date note under section 801 of this title.

SAVINGS PROVISIONS

Repeal of this section not to affect or abate any prosecutions for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such repeal, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91-513, set out as a Savings Provisions note under section 321 of this title.

§ 360b. New animal drugs

(a) Unsafe new animal drugs and animal feed containing such drugs; conditions of safety; exemption of drugs for research

(1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for the purposes of section 351(a)(5) and section 342(a)(2)(D) of this title unless—

(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such use or intended use of such drug,

(B) such drug, its labeling, and such use conform to such approved application, and

(C) in the case of a new animal drug subject to subsection (n) of this section and not exempted therefrom by regulations it is from a batch with respect to which a certificate or

release issued pursuant to subsection (n) of this section is in effect with respect to such drug.

A new animal drug shall also be deemed unsafe for such purposes in the event of removal from the establishment of a manufacturer, packer, or distributor of such drug for use in the manufacture of animal feed in any State unless at the time of such removal such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or notice from the Secretary, to the effect that, with respect to the use of such drug in animal feed, such consignee—

(i) is the holder of an approved application under subsection (m) of this section; or

(ii) will, if the consignee is not a user of the drug, ship such drug only to a holder of an approved application under subsection (m) of this section.

(2) An animal feed bearing or containing a new animal drug shall, with respect to any particular use or intended use of such animal feed, be deemed unsafe for the purposes of section 351(a)(6) of this title unless—

(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such drugs, as used in such animal feed,

(B) there is in effect an approval of an application pursuant to subsection (m)(1) of this section with respect to such animal feed, and

(C) such animal feed, its labeling, and such use conform to the conditions and indications of use published pursuant to subsection (i) of this section and to the application with respect thereto approved under subsection (m) of this section.

(3) A new animal drug or an animal feed bearing or containing a new animal drug shall not be deemed unsafe for the purposes of section 351(a)(5) or (6) of this title if such article is for investigational use and conforms to the terms of an exemption in effect with respect thereto under subsection (j) of this section.

(b) Filing application for uses of new animal drug; contents

Any person may file with the Secretary an application with respect to any intended use or uses of a new animal drug. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe and effective for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof, of any animal feed for use in or on which such drug is intended, and of the edible portions or products (before or after slaughter) of animals to which such drug (directly or in or on animal feed) is intended to be administered, as the Secretary may require; (6) specimens of the labeling proposed to be used for such drug, or in case such drug is intended for use in animal feed, proposed labeling appropriate for such use, and specimens of the labeling for the drug to be manufactured, packed, or distributed by the applicant; (7) a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use; and (8) the proposed tolerance or withdrawal period or other use restrictions for such drug if any tolerance or withdrawal period or other use restrictions are required in order to assure that the proposed use of such drug will be safe.

(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

Within one hundred and eighty days after the filing of an application pursuant to subsection (b) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either (1) issue an order approving the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies, or (2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question whether such application is approvable. If the applicant elects to accept the opportunity for a hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(d) Grounds for refusing application; approval of application; factors; "substantial evidence" defined

(1) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that—

(A) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof;

(B) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions;

(C) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity;

(D) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions;

(E) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of

substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(F) upon the basis of the information submitted to him as part of the application or any other information before him with respect to such drug, the tolerance limitation proposed, if any, exceeds that reasonably required to accomplish the physical or other technical effect for which the drug is intended;

(G) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; or

(H) such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the foregoing provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h) of this section), in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals;

he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearings, the Secretary finds that subparagraphs (A) through (H) do not apply, he shall issue an order approving the application.

(2) In determining whether such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, the Secretary shall consider, among other relevant factors, (A) the probable consumption of such drug and of any substance formed in or on food because of the use of such drug, (B) the cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substance, (C) safety factors which in the opinion of experts, qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data, and (D) whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice. Any order issued under this subsection refusing to approve an application shall state the findings upon which it is based.

(3) As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including field investigation, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to health of man or animals

(1) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) of this section with respect to any new animal drug if the Secretary finds—

(A) that experience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved;

(B) that new evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved or that subparagraph (H) of paragraph (1) of subsection (d) of this section applies to such drug;

(C) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that such drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(D) that the application contains any untrue statement of a material fact; or

(E) that the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application unless he has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application. The supplemental application shall be treated in the same manner as the original application.

If the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the health of man or of the animals for which such drug is intended, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence to suspend the approval of an application shall not be delegated.

(2) The Secretary may also, after due notice and opportunity for hearing to the applicant, issue an order withdrawing the approval of an application with respect to any new animal drug under this section if the Secretary finds—

(A) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under subsection (1) of this section, or

the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection;

(B) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

(C) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(3) Any order under this subsection shall state the findings upon which it is based.

(f) Revocation of order refusing, withdrawing or suspending approval of application

Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d), (e), or (m) of this section refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Service of orders

Orders of the Secretary issued under this section (other than orders issuing, amending, or repealing regulations) shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last known address in the records of the Secretary.

(h) Appeal from order

An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application filed under subsection (b) or (m) of this section. The provisions of subsection (h) of section 355 of this title shall govern any such appeal.

(i) Publication in Federal Register; effective date and revocation or suspension of regulation

When a new animal drug application filed pursuant to subsection (b) of this section is approved, the Secretary shall by notice, which upon publication shall be effective as a regulation, publish in the Federal Register the name and address of the applicant and the conditions and indications of use of the new animal drug covered by such application, including any tolerance and withdrawal period or other use restrictions and, if such new animal drug is intended for use in animal feed, appropriate purposes and conditions of use (including special labeling requirements) applicable to any animal feed for use in which such drug is approved, and such other information, upon the basis of which such application was approved, as the Secretary deems necessary to assure the safe and effective use of such drug. Upon withdrawal of approval of such new animal drug application or upon its suspension, the Secretary shall forthwith revoke or suspend, as the case may be, the regulation published pursuant to this subsection (i) insofar as it is based on the approval of such application.

(j) Exemption of drugs for research; discretionary and mandatory conditions

To the extent consistent with the public health, the Secretary shall promulgate regulations for exempting from the operation of this section new animal drugs, and animal feeds bearing or containing new animal drugs, intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of animal drugs. Such regulations may, in the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such article, of data (including but not limited to analytical reports by investigators) obtained as a result of such investigational use of such article, as the Secretary finds will enable him to evaluate the safety and effectiveness of such article in the event of the filing of an application pursuant to this section. Such regulations, among other things, shall set forth the conditions (if any) upon which animals treated with such articles, and any products of such animals (before or after slaughter), may be marketed for food use.

(k) Food containing new animal drug considered unadulterated while approval of application for such drug is effective

While approval of an application for a new animal drug is effective, a food shall not, by reason of bearing or containing such drug or any substance formed in or on the food because of its use in accordance with such application (including the conditions and indications of use prescribed pursuant to subsection (i) of this section), be considered adulterated within the meaning of clause (1) of section 342(a) of this title.

(l) Records and reports; required information; regulations and orders; examination of data; access to records

(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) of this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for

the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(m)(1) Filing application for uses of animal feed containing new animal drug; contents

Any person may file with the Secretary an application with respect to any intended use or uses of an animal feed bearing or containing a new animal drug. Such person shall submit to the Secretary as part of the application (A) a full statement of the composition of such animal feed, (B) an identification of the regulation or regulations (relating to the new animal drug or drugs to be used in such feed), published pursuant to subsection (i) of this section, on which he relies as a basis for approval of his application with respect to the use of such drug in such feed, (C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such animal feed, (D) specimens of the labeling proposed to be used for such animal feed, and (E) if so requested by the Secretary, samples of such animal feed or components thereof.

(2) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

Within ninety days after the filing of an application pursuant to paragraph (1) of this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either (A) issue an order approving the application if he then finds that none of the grounds for denying approval specified in paragraph (3) applies, or (B) give the applicant notice of an opportunity for a hearing before the Secretary under paragraph (3) on the question whether such application is approvable. The procedure governing such a hearing shall be the procedure set forth in the last two sentences of subsection (c) of this section.

(3) Grounds for refusing application; approval of application; approval effective during existence of subsection (i) regulation

If the Secretary, after due notice to the applicant in accordance with paragraph (2) and giving him an opportunity for a hearing in accordance with such paragraph, finds, on the basis of information submitted to him as part of the application or on the basis of any other information before him—

(A) that there is not in effect a regulation under subsection (i) of this section (identified in such application) on the basis of which such application may be approved;

(B) that such animal feed (including the proposed use of any new animal drug therein or thereon) does not conform to an applicable regulation published pursuant to subsection (i) of this section referred to in the application, or that the purposes and conditions or indications of use prescribed, recommended, or suggested in the labeling of such feed do not conform to the applicable purposes and conditions or indications of use (including warnings) published pursuant to subsection (i) of this section or such labeling omits or fails to conform to other applicable information published pursuant to subsection (i) of this section;

(C) that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such animal feed are inadequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

(D) that, based on a fair evaluation of all material facts, such labeling is false or misleading in any particular;

he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that subparagraphs (A) through (D) do not apply, he shall issue an order approving the application. An order under this subsection approving an application with respect to an animal feed bearing or containing a new animal drug shall be effective only while there is in effect a regulation pursuant to subsection (i) of this section, on the basis of which such application (or a supplement thereto) was approved, relating to the use of such drug in or on such feed.

(4) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to health of man or animals

(A) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application with respect to any animal feed under this subsection if the Secretary finds—

(i) that the application contains any untrue statement of a material fact; or

(ii) that the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application unless he has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application. The supplemental application shall be treated in the same manner as the original application.

If the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the health of man or of the animals for which such animal feed is intended, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence shall not be delegated.

(B) The Secretary may also, after due notice and opportunity for hearing to the applicant, issue an order withdrawing the approval of an application with respect to any animal feed under this subsection if the Secretary finds—

(i) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order

under paragraph (5)(A) of this subsection, or the applicant has refused to permit access to, or copying or verification of, such records as required by subparagraph (B) of such paragraph;

(ii) that on the basis of new information before him, evaluated together with the evidence before him when such application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such animal feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from the Secretary, specifying the matter complained of; or

(iii) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such animal feed, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(C) Any order under paragraph (4) of this subsection shall state the findings upon which it is based.

(5) Records and reports; regulations and orders; access to records

In the case of an animal feed for which an approval of an application filed pursuant to this subsection is in effect—

(A) the applicant shall establish and maintain such records, and make such reports to the Secretary, or (at the option of the Secretary) to the appropriate person or persons holding an approved application filed under subsection (b) of this section, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section or paragraph (4) of this subsection.

(B) every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(n)(1) Certification of new drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin; release prior to certification

The Secretary, pursuant to regulations promulgated by him, shall provide for the certificatin of batches of a new animal drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof. A batch of any such drug shall be certified if an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug and such drug has the characteristics of identity and such batch has the characteristics of strength, quality, and purity upon the basis of which the application was approved, but shall not otherwise be certified. Prior to the effective date of such regulations the Secretary, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof.

(2) Regulations

Regulations providing for such certifications shall contain such provisions as are necessary to carry out the purposes of this subsection including provisions prescribing—

(A) tests and methods of assay to determine compliance with applicable standards of identity and of strength, quality, and purity;

(B) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof;

(C) administration and procedure; and

(D) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service.

Such regulations shall prescribe only such tests and methods of assay as will provide for certification or rejection within the shortest time consistent with the purposes of this subsection.

(3) Exemption of drugs from subsection (n) requirements; applicability of section 357(c) of this title

Whenever, in the judgment of the Secretary, the requirements of this subsection with respect to any drug or class of drugs are not necessary to insure that such drug conforms to the standards of identity, strength, quality, and purity applicable thereto under paragraph (1) of this subsection, the Secretary shall promulgate regulations exempting such drug or class of drugs from such requirements. The provisions of subsection (c) of section 357 of this title (other than the first sentence thereof) shall apply under this paragraph.

(4) Exemption of drugs stored, processed, and labeled at other than manufacturing establishments or used in manufacture of other drugs

The Secretary shall promulgate regulations exempting from any requirement of this subsection—

(A) drugs which are to be stored, processed, labeled, or repacked at establishments other than those where manufactured, on condition that such drugs comply with all such requirements upon removal from such establishments; and

(B) drugs which conform to applicable standards of identity, strength, quality, and purity prescribed pursuant to this subsection and are intended for use in manufacturing other drugs.

(5) Procedure for issuance, amendment, or repeal of regulations

On petition of any interested person for the issuance, amendment, or repeal of any regulation contemplated by this subsection, the procedure shall be in accordance with subsection (f) of section 357 of this title.

(6) Determination of compliance with sections 351(b) and 352(g) of this title

Where any drug is subject to this subsection and not exempted therefrom by regulations, the compliance of such drug with sections 351(b) and 352(g) of this title shall be determined by the application of the standards of strength, quality, and purity applicable under paragraph (1) of this subsection, the tests and methods of assay applicable under provisions of regulations referred to in paragraph (2)(A) of this subsection, and the requirements of packaging and labeling on the basis of which the application with respect to such drug filed under subsection (b) of this section was approved.

(June 25, 1968, ch. 675, § 512, as added July 13, 1968, Pub. L. 90-399, § 101(b), 82 Stat. 343.)

EFFECTIVE DATE AND TRANSITIONAL PROVISIONS

Section 108 of Pub. L. 90-399 provided that:

"(a) Except as otherwise provided in this section, the amendments made by the foregoing sections [see Short Title note under this section] shall take effect on the first day of the thirteenth calendar month which begins after the date of enactment of this Act [July 13, 1968].

"(b)(1) As used in this subsection, the term 'effective date' means the effective date specified in subsection (a) of this section; the term 'basic Act' means the Federal Food, Drug, and Cosmetic Act [this chapter]; and other terms used both in this section and the basic Act shall have the same meaning as they have, or had, at the time referred to in the context, under the basic Act.

"(2) Any approval, prior to the effective date, of a new animal drug or of an animal feed bearing or containing a new animal drug, whether granted by approval of a new-drug application, master file, antibiotic regulation, or food additive regulations, shall continue in effect, and shall be subject to change in accordance with the provisions of the basic Act as amended by this Act [see Short Title note under this section].

"(3) In the case of any drug (other than a drug subject to section 512(n) of the basic Act as amended by this Act) [subsection (n) of this section] intended for use in animals other than man which, on October 9, 1962, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act [section 321(p) of this title] as then in force, and (C) was not covered by an effective application under section 505 of that Act [section 355 of this title], the words 'effectiveness' and 'effective' contained in section 201(w) as added by this Act to the basic Act [section 321(w) of this title] shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day.

"(4) Regulations providing for fees (and advance deposits to cover fees) which on the day preceding the effective date applicable under subsection (a) of this section were in effect pursuant to section 507 of the basic Act [section 357 of this title] shall, except as the Secretary may otherwise prescribe, be deemed to apply also under section 512(n) of the basic Act [subsection (n) of this section], and appropriations of fees (and of advance deposits to cover fees) available for the purposes specified in such section 507 [section 357 of this title] as in effect prior to the effective date shall also be available for the purposes specified in section 512(n) [subsection (n) of this section], including preparatory work or proceedings prior to that date."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 331, 342, 351, 360, 381, 827 of this title.

§ 360c. Classification of devices intended for human use

(a) Classes of devices

(1) There are established the following classes of devices intended for human use:

(A) Class I, General Controls—

(i) A device for which the controls authorized by or under section 351, 352, 360 360f, 360h, 360i, or 360j of this title or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

(B) Class II, Performance Standards—A device which cannot be classified as a class I device because the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, for which there is sufficient information to establish a performance standard to provide such assurance, and for which it is therefore necessary to establish for the device a performance standard under section 360d of this title to provide reasonable assurance of its safety and effectiveness.

(C) Class III, Premarket Approval—A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title are sufficient to provide reasonable assurance of the safety and effectiveness of the device and (II) cannot be classified as a class II device because insufficient information exists for the establishment of a performance standard to provide reasonable assurance of its safety and effectiveness, and

(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and ef-

fectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

(2) For purposes of this section and sections 360d and 360e of this title, the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditons of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

(3)(A) Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 360d and 360e of this title, to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

(B) If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A))—

(i) which is sufficient to determine the effectiveness of a device, and

(ii) from which it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device,

then, for purposes of this section and sections 360d and 360e of this title, the Secretary may authorize the effectiveness of the device to be determined on the basis of such evidence.

(b) Classification panels

(1) For purposes of—

(A) determining which devices intended for human use should be subject to the requirements of general controls, performance standards, or premarket approval, and

(B) providing notice to the manufacturers and importers of such devices to enable them to prepare for the application of such requirements to devices manufactured or imported by them,

the Secretary shall classify all such devices (other than devices classified by subsection (f) of this section) into the classes established by subsection (a) of this section. For the purpose of securing recommendations with respect to the classification of devices, the Secretary shall establish panels of experts or use panels of experts established before May 28, 1976, or both. Section 14 of the Federal Advisory Committee Act shall not apply to the duration of a panel established under this paragraph.

(2) The Secretary shall appoint to each panel established under paragraph (1) persons who are qualified by training and experience to evaluate the safety and effectiveness of the devices to be referred to the panel and who, to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such devices. The Secretary shall make appointments to each panel so that each panel shall consist of members with adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. In addition, each panel shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter may be a member of any panel. The Secretary shall designated one of the members of each panel to serve as chairman thereof.

(3) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, but not at rates exceeding the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day so engaged, including traveltime; and while so serving away from their homes or regular places of business each member may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703(b) of title 5, for persons in the Government service employed intermittently.

(4) The Secretary shall furnish each panel with adequate clerical and other necessary assistance.

(c) Classification panel organization and operation

(1) The Secretary shall organize the panels according to the various fields of clinical medicine and fundamental sciences in which devices intended for human use are used. The Secretary shall refer a device to be classified under this section to an appropriate panel established or authorized to be used under subsection (b) of this section for its review and for its recommendation respecting the classification of the device. The Secretary shall by regulation prescribe the procedure to be followed by the panels in making their reviews and recommendations. In making their reviews of devices, the panels, to the maximum extent practicable, shall provide an opportunity for interested persons to submit data and views on the classification of the devices.

(2)(A) Upon completion of a panel's review of a device referred to it under paragraph (1), the panel shall, subject to subparagraphs (B) and (C), submit to the Secretary its recommendation for the classification of the device. Any such recommendation shall (i) contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the recommendation is made, and (ii) to the extent practicable, include a recommendation for the assignment of a priority for the application of

the requirements of section 360d or 360e of this title to a device recommended to be classified in class II or class III.

(B) A recommendation of a panel for the classification of a device in class I shall include a recommendation as to whether the device should be exempted from the requirements of section 360, 360i, or 360j(f) of this title.

(C) In the case of a device which has been referred under paragraph (1) to a panel, and which—

(i) is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life, and

(ii)(I) has been introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or

(II) is within a type of device which was so introduced or delivered before such date and is substantially equivalent to another device within that type,

such panel shall recommend to the Secretary that the device be classified in class III unless the panel determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. If a panel does not recommend that such a device be classified in class III, it shall in its recommendation to the Secretary for the classification of the device set forth the reasons for not recommending classification of the device in such class.

(3) The panels shall submit to the Secretary within one year of the date funds are first appropriated for the implementation of this section their recommendations respecting all devices of a type introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976.

(d) Panel recommendation; publication; priorities

(1) Upon receipt of a recommendation from a panel respecting a device, the Secretary shall publish in the Federal Register the panel's recommendation and a proposed regulation classifying such device and shall provide interested persons an opportunity to submit comments on such recommendation and the proposed regulation. After reviewing such comments, the Secretary shall, subject to paragraph (2), by regulation classify such device.

(2)(A) A regulation under paragraph (1) classifying a device in class I shall prescribe which, if any, of the requirements of section 360, 360i, or 360j(f) of this title shall not apply to the device. A regulation which makes a requirement of section 360, 360i, or 360j(f) of this title inapplicable to a device shall be accompanied by a statement of the reasons of the Secretary for making such requirement inapplicable.

(B) A device described in subsection (c)(2)(C) of this section shall be classified in class III unless the Secretary determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. A proposed regulation under paragraph (1) classifying such a device in a class other than class III shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for not classifying such device in such class and an identification of the risks to health (if any) presented by such device.

(3) In the case of devices classified in class II and devices classified under this subsection in class III and described in section 360e(b)(1) of this title the Secretary may establish priorities which, in his discretion, shall be used in applying sections 360d and 360e of this title, as appropriate, to such devices.

(e) Classification changes

Based on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an interested person, by regulation (1) change such device's classification, and (2) revoke, because of the change in classification, any regulation or requirement in effect under section 360d or 360e of this title with respect to such device. In the promulgation of such a regulation respecting a device's classification, the Secretary may secure from the panel to which the device was last referred pursuant to subsection (c) of this section a recommendation respecting the proposed change in the device's classification and shall publish in the Federal Register any recommendation submitted to the Secretary by the panel respecting such change. A regulation under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 360d of this title for such device.

(f) Initial classification of certain devices

(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, is classified in class III unless—

(A) the device—

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b) of this section, or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type, or

(B) the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) classifying the device in class I or II.

(2)(A) The manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition.

(B)(i) Upon determining that a petition does not contain any deficiency which prevents the

Secretary from making a decision on the petition, the Secretary shall refer the petition to an appropriate panel established or authorized to be used under subsection (b) of this section. A panel to which such a petition has been referred shall not later than ninety days after the referral of the petition make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed. In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the panel shall recommend that the petition be denied unless the panel determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. If the panel recommends that such petition be approved, it shall in its recommendation to the Secretary set forth its reasons for such recommendation.

(ii) The requirements of paragraphs (1) and (2) of subsection (c) of this section (relating to opportunities for submission of data and views and recommendations respecting priorities and exemptions from sections 360, 360i, and 360j(f) of this title) shall apply with respect to consideration by panels of petitions submitted under subparagraph (A).

(C)(i) Within ninety days from the date the Secretary receives the recommendation of a panel respecting a petition (but not later than 210 days after the filing of such petition) the Secretary shall by order deny or approve the petition. If the Secretary approves the petition, the Secretary shall order the classification of the device into class I or class II in accordance with the criteria prescribed by subsection (a)(1)(A) or (a)(1)(B) of this section. In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall deny the petition unless the Secretary determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. An order approving such petition shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for approving the petition and an identification of the risks to health (if any) presented by the device to which such order applies.

(ii) The requirements of paragraphs (1) and (2)(A) of subsection (d) of this section (relating to publication of recommendations, opportunity for submission of comments, and exemption from sections 360, 360i, and 360j(f) of this title) shall apply with respect to action by the Secretary on petitions submitted under subparagraph (A).

(g) Information

Within sixty days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this chapter, the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this chapter applicable to the device.

(h) Definitions

For purposes of this section and sections 351, 360, 360d, 360e, 360f, 360i, and 360j of this title

(1) a reference to "general controls" is a reference to the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title,

(2) a reference to "class I", "class II", or "class III" is a reference to a class of medical devices described in subparagraph (A), (B), or (C) of subsection (a)(1) of this section, and

(3) a reference to a "panel under section 360c of this title" is a reference to a panel established or authorized to be used under this section.

(June 25, 1938, ch. 675, § 513, as added May 28, 1976, Pub. L. 94-295, § 2, 90 Stat. 540.)

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (b)(1), is Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, which is set out in Appendix to Title 5, Government Organization and Employees.

The General Schedule, referred to in subsec. (b)(3), is set out under section 5332 of Title 5, Government Organization and Employees.

Provisions formerly contained in section 5703(b) of title 5, referred to in subsec. (b)(3), were retained in section 5703 of title 5 notwithstanding the amendment of that section by Pub. L. 94-22, § 4, May 19, 1975, 89 Stat. 85, which eliminated lettered subsections.

SHORT TITLE OF 1976 AMENDMENT

Pub. L. 94-295, § 1(a), May 28, 1976, 90 Stat. 539, provided that: "This Act [enacting sections 360c to 360k, 379, and 379a of this title and section 3512 of Title 42, The Public Health and Welfare, and amending sections 321, 331, 334, 351, 352, 358, 360, 374, 376, and 381 of this title and section 55 of Title 15, Commerce and Trade] may be cited as the 'Medical Device Amendments of 1976'."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 351, 360, 360d, 360e, 360f, 360g, 360j of this title.

§ 360d. Performance standards

(a) Reasonable assurance of safe and effective performance; periodic evaluation

(1) The Secretary may be regulation, promulgated in accordance with this section, establish a performance standard for a class II device. A class III device may also be considered a class II device for purposes of establishing a standard for the device under this section if the device has been reclassified as a class II device under a regulation under section 360c(e) of this title but such regulation provides that the reclassification is not to take effect until the effective date of such a standard for the device.

(2) A performance standard established under this section for a device—

(A) shall include provisions to provide reasonable assurance of its safe and effective performance;

(B) shall, where necessary to provide reasonable assurance of its safe and effective performance, include—

(i) provisions respecting the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to such systems,

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of the device to the standard, provisions for the testing (on a sample basis or, if necessary, on an individual basis) by the Secretary or by another person at the direction of the Secretary,

(iii) provisions for the measurement of the performance characteristics of the device,

(iv) provisions requiring that the results of each or of certain of the tests of the device required to be made under clause (ii) show that the device is in conformity with the portions of the standard for which the test or tests were required, and

(v) a provision requiring that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 360j(e) of this title; and

(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device.

(3) The Secretary shall provide for periodic evaluation of performance standards established under this section to determine if such standards should be changed to reflect new medical, scientific, or other technological data.

(4) In carrying out his duties under this section, the Secretary shall, to the maximum extent practicable—

(A) use personnel, facilities, and other technical support available in other Federal agencies,

(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities, and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, or consumer organizations who in his judgment can make a significant contribution.

(b) Initiation of proceedings for development of performance standards; notice of opportunity to submit requests; requests

(1) A proceeding for the development of a performance standard for a device shall be initiated by the Secretary by the publication in the Federal Register of notice of the opportunity to submit to the Secretary a request (within fifteen days of the date of the publication of the notice) for a change in the classification of the device based on new information relevant to its classification.

(2) If, after publication of a notice pursuant to paragraph (1) the Secretary receives a request for a change in the device's classification, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 360c of this title, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 360c(e) of this title.

(c) Invitation for standards

(1) If, after the publication of a notice under subsection (b) of this section, no action is required under paragraph (2) of such subsection or the Secretary denies a request to change the classification of the device with respect to which such notice was published, the Secretary shall publish in the Federal Register a notice inviting any person, including any Federal agency, to—

(A) submit to the Secretary, within sixty days after the date of publication of the notice, an existing standard as a proposed performance standard for such device, or

(B) offer, within sixty days after the date of publication of the notice, to develop such a proposed standard.

(2) A notice published pursuant to paragraph (1) for an offer for the development of a proposed performance standard for a device—

(A) shall specify a period within which the standard is to be developed, which period may be extended by the Secretary for good cause shown; and

(B) shall include—

(i) a description or other designation of the device,

(ii) a statement of the nature of the risk or risks associated with the use of the device and intended to be controlled by a performance standard,

(iii) a summary of the data on which the Secretary has found a need for initiation of the proceeding to develop a performance standard, and

(iv) identification of any existing performance standard known to the Secretary which may be relevant to the proceeding.

(3) The Secretary shall by regulation require that an offeror of an offer to develop a proposed performance standard submit (and if the offeror is a business entity, require that appropriate directors, officers, and employees of, and consultants to, the business entity submit) to the Secretary such information concerning the offeror as the Secretary determines is relevant with respect to the offeror's qualifications to develop a proposed performance standard for a device, including information respecting the offeror's financial stability, expertise, and experience, and any potential conflicts of interest, including financial interest in the device for which the proposed standard is to be developed, current industrial or commercial affiliates of the offeror, current sources of financial support for research, and business entities in which the offeror has a financial interest, which may be relevant with respect to the offeror's qualifications. Such information submitted by an offeror may not be made public by the Secretary unless required by section 552 of title 5, except that in the case of information submitted by an offeror whose offer has been accepted, the Secretary shall make such information (other than information which because of subsection (b)(4)

of section 552 of title 5, is exempt from disclosure pursuant to subsection (a) of such section) public at the time the offer is accepted.

(4) If the Secretary determines that a performance standard can be developed by any Federal agency (including an agency within the Department of Health, Education, and Welfare), the Secretary may—

(A) if such determination is made with respect to an agency within such Department, develop such a standard in lieu of accepting any offer to develop such a standard pursuant to a notice published pursuant to this subsection, or

(B) if such determination is made with respect to any other agency, authorize such agency to develop such a standard in lieu of accepting any such offer.

In making such a determination respecting a Federal agency, the Secretary shall take into account the personnel and expertise within such agency. The requirements described in subparagraphs (B) and (C) of subsection (e)(4) of this section shall apply to development of a standard under this paragraph.

(d) Acceptance of certain existing standards

(1) If the Secretary—

(A) determines that a performance standard has been issued or adopted or is being developed by any Federal agency or by any other qualified entity or receives a performance standard submitted pursuant to a notice published pursuant to subsection (c) of this section, and

(B) determines that such performance standard is based upon scientific data and information and has been subjected to scientific consideration,

he may, in lieu of accepting any offer to develop such a standard pursuant to a notice published pursuant to subsection (c) of this section, accept such standard as a proposed performance standard for such device or as a basis upon which a proposed performance standard may be developed.

(2) If a standard is submitted to the Secretary pursuant to a notice published pursuant to subsection (c) of this section and the Secretary does not accept such standard, he shall publish in the Federal Register notice of that fact together with the reasons therefor.

(e) Acceptance of offer to develop standards

(1) Except as provided by subsections (c)(4) and (d) of this section, the Secretary shall accept one, and may accept more than one, offer to develop a proposed performance standard for a device pursuant to a notice published pursuant to subsection (c) of this section if he determines that (A) the offeror is qualified to develop such a standard and is technically competent to undertake and complete the development of an appropriate performance standard within the period specified in the notice, and (B) the offeror will comply with procedures prescribed by regulations of the Secretary under paragraph (4) of this subsection. In determining the qualifications of an offeror to develop a standard, the Secretary shall take into account the offeror's financial stability, expertise, experience, and any potential conflicts of interests (including financial interest in the device for which such standard is to be developed) and other information submitted pursuant to subsection (c)(3) of this section, which may be relevant with respect to the offeror's qualifications.

(2) The Secretary shall publish in the Federal Register the name and address of each person whose offer is accepted under paragraph (1) and a summary of the terms of such offer as accepted.

(3) If such an offer is accepted, the Secretary may, upon application which may be made prior to the acceptance of the offer, agree to contribute to the offeror's cost in developing a proposed standard if the Secretary determines that such contribution is likely to result in a more satisfactory standard than would be developed without such contribution. The Secretary shall by regulation prescribe the items of cost in which he will participate, except that such items may not include the cost of construction (except minor remodeling) or the acquisition of land or buildings. Payments to an offerer under this paragraph may be made without regard to section 529 of title 31.

(4) The Secretary shall prescribe regulations governing the development of proposed standards by persons whose offers are accepted under paragraph (1). Such regulations shall, notwithstanding subsection (b)(A) of section 553 of title 5, be promulgated in accordance with the requirements of that section for notice and opportunity for participation and shall—

(A) require that performance standards proposed for promulgation be supported by such test data or other documents or materials as the Secretary may reasonably require to be obtained;

(B) require that notice be given to interested persons of the opportunity to participate in the development of such performance standards and require the provision of such opportunity;

(C) require the maintenance of records to disclose (i) the course of the development of performance standards proposed for promulgation, (ii) the comments and other information submitted by any person in connection with such development, including comments and information with respect to the need for such performance standards, and (iii) such other matters as may be relevant to the evaluation of such performance standards;

(D) provide that the Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and other records, relevant to the expenditure of any funds contributed by the Secretary under paragraph (3); and

(E) require the submission of such periodic reports as the Secretary may require to disclose the course of the development of performance standards proposed for promulgation.

(5) If an offer is made pursuant to a notice published pursuant to subsection (c) of this section and the Secretary does not accept such offer, he shall publish in the Federal Register notice of that fact together with the reasons therefor.

(f) Development of standards by Secretary after publication of notice inviting submission or offer of standards

If the Secretary has published a notice pursuant to subsection (c) of this section and—

(1) no person makes an offer or submits a standard pursuant to the notice;

(2) the Secretary has not accepted an existing performance standard under subsection (d) of this section or accepted an offer to develop a proposed performance standard pursuant to the notice; or

(3) the Secretary has accepted an offer or offers to develop a proposed performance standard, but determines thereafter that—

(A) the offeror under each such offer is unwilling or unable to continue the development of the performance standard which was the subject of the offer or offers, or

(B) the performance standard which has been developed is not satisfactory,

and publishes notice of that determination in the Federal Register together with his reasons therefor;

then the Secretary may proceed to develop a proposed performance standard. The authority provided by this subsection is in addition to the authority provided by subsection (c)(4) of this section. The requirements described in subparagraphs (B) and (C) of subsection (e)(4) of this section shall apply to the development of a standard by the Secretary under this subsection.

(g) Establishment of standards; advisory committee

(1)(A) After publication pursuant to subsection (c) of this section of a notice respecting a performance standard for a device, the Secretary shall either—

(i) publish, in the Federal Register in a notice of proposed rulemaking, a proposed performance standard for the device (I) developed by an offeror under such notice and accepted by the Secretary, (II) developed under subsection (c)(4) of this section, (III) accepted by the Secretary under subsection (d) of this section, or (IV) developed by him under subsection (f) of this section, or

(ii) issue a notice in the Federal Register that the proceeding is terminated together with the reasons for such termination.

(B) If the Secretary issues under subparagraph (A)(ii) a notice of termination of a proceeding to establish a performance standard for a device, he shall (unless such notice is issued because the device is a banned device under section 360f of this title) initiate a proceeding under section 360c(e) of this title to reclassify the device subject to the proceeding terminated by such notice.

(2) A notice of proposed rulemaking for the establishment of a performance standard for a device published under paragraph (1)(A)(i) shall set forth proposed findings with respect to the degree of the risk of illness or injury designed to be eliminated or reduced by the proposed standard and the benefit to the public from the device.

(3)(A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory committee under paragraph (5), the Secretary shall (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (2), or (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 360f of this title) initiate a proceeding under section 360c(e) of this title to reclassify the device subject to the proceeding terminated by such notice.

(B) A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless (i) the Secretary determines that an earlier effective date is necessary for the protection of the public health and safety, or (ii) such standard has been established for a device which, effective upon the effective date of the standard, has been reclassified from class III to class II. Such date or dates shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade.

(4)(A) The Secretary, upon his own initiative or upon petition of an interested person may by regulation, promulgated in accordance with the requirements of paragraphs (2) and (3)(B) of this subsection, amend or revoke a performance standard.

(B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if he determines, after affording all interested persons an opportunity for an informal hearing, that making it so effective is in the public interest. A proposed amendment of a performance standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device which conforms to such standard without the change or changes provided by such proposed amendment.

(5)(A) The Secretary—

(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

(ii) shall, upon the request of an interested person unless the Secretary finds the request to be without good cause or the request is made after the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,

to an advisory committee of experts, established pursuant to subparagraph (B), for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subparagraph to an advisory committee, the Secretary shall provide the advisory com-

mittee with the data and information on which such proposed regulation is based. The advisory committee shall, within sixty days of the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

(B) The Secretary shall establish advisory committees (which may not be panels under section 360c of this title) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter. Each such committee shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Members of an advisory committee who are not officers or employees of the United States, while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government service employed intermittently. The Secretary shall designate one of the members of each advisory committee to serve as chairman thereof. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

(June 25, 1938, ch. 675, § 514, as added May 28, 1976, Pub. L. 94-295, § 2, 90 Stat. 546, and amended Oct. 8, 1976, Pub. L. 94-460, title III, § 304, 90 Stat. 1960.)

REFERENCES IN TEXT

The General Schedule, referred to in subsec. (g)(5)(B), is set out under section 5332 of Title 5, Government Organization and Employees.

AMENDMENTS

1976—Subsec. (a). Pub. L. 94-460 redesignated former pars. (4) and (5) as (3) and (4), respectively. Section as originally enacted contained no par. (3).

TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of two year period following Jan. 5, 1973, and advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of two year period beginning on the date of their establishment, unless in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such two year period, or in the case of a committee established by Congress, its duration is otherwise provided by law, see section 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 351, 352, 360, 360c, 360e, 360g, 360j, 381 of this title.

§ 360e. Premarket approval

(a) General requirement

A class III device—

(1) which is subject to a regulation promulgated under subsection (b) of this section; or

(2) which is a class III device because of section 360c(f) of this title,

is required to have, unless exempt under section 360j(g) of this title, an approval under this section of an application for premarket approval.

(b) Regulation to require premarket approval

(1) In the case of a class III device which—

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976; or

(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type,

the Secretary shall by regulation, promulgated in accordance with this subsection, require that such device have an approval under this section of an application for premarket approval.

(2)(A) A proceeding for the promulgation of a regulation under paragraph (1) respecting a device shall be initiated by the publication in the Federal Register of a notice of proposed rulemaking. Such notice shall contain—

(i) the proposed regulation;

(ii) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved application for premarket approval and the benefit to the public from use of the device;

(iii) opportunity for the submission of comments on the proposed regulation and the proposed findings; and

(iv) opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

(B) If, within fifteen days after publication of a notice under subparagraph (A), the Secretary receives a request for a change in the classification of a device, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 360c of this title, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 360c(e) of this title.

(3) After the expiration of the period for comment on a proposed regulation and proposed findings published under paragraph (2) and after consideration of comments submitted on

such proposed regulation and findings, the Secretary shall (A) promulgate such regulation and publish in the Federal Register findings on the matters referred to in paragraph (2)(A)(ii), or (B) publish a notice terminating the proceeding for the promulgation of the regulation together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 360f of this title) initiate a proceeding under section 360c(e) of this title to reclassify the device subject to the proceeding terminated by such notice.

(4) The Secretary, upon his own initiative or upon petition of an interested person, may by regulation amend or revoke any regulation promulgated under this subsection. A regulation to amend or revoke a regulation under this subsection shall be promulgated in accordance with the requirements prescribed by this subsection for the promulgation of the regulation to be amended or revoked.

(c) Application for premarket approval

(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require.

(2) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary shall refer such application to the appropriate panel under section 360c of this title for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.

(d) Action on application for premarket approval

(1)(A) As promptly as possible, but in no event later than one hundred and eighty days after the receipt of an application under subsection (c) of this section (except as provided in section 360j(*l*)(3)(D)(ii) of this title or unless, in accordance with subparagraph (B)(i), an additional period as agreed upon by the Secretary and the applicant), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

(i) issue an order approving the application if he finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

(ii) deny approval of the application if he finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

(B)(i) The Secretary may not enter into an agreement to extend the period in which to take action with respect to an application submitted for a device subject to a regulation promulgated under subsection (b) of this section unless he finds that the continued availability of the device is necessary for the public health.

(ii) An order approving an application for a device may require as a condition to such approval that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 360j(e) of this title.

(2) The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the application and any other information before him with respect to such device, the Secretary finds that—

(A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(C) the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 360j(f) of this title;

(D) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(E) such device is not shown to conform in all respects to a performance standard in effect under section 360d of this title compliance with which is a condition to approval of the application and there is a lack of adequate information to justify the deviation from such standard.

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary).

(3) An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g) of this section, and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g) of this section, of an order of the Secretary approving an application.

(e) Withdrawal of approval of application for premarket approval

(1) The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 360c of this title, and after due notice and opportunity for informal hearing to the holder of an approved application for a device, issue an order withdrawing approval of the application if the Secretary finds—

(A) that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(B) on the basis of new information before him with respect to such device, evaluated together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(C) that the application contained or was accompanied by an untrue statement of a material fact;

(D) that the applicant (i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 360i(a) of this title, (ii) has refused to permit access to, or copying or verification of, such records as required by section 374 of this title, or (iii) has not complied with the requirements of section 360 of this title;

(E) on the basis of new information before him with respect to such device, evaluated together with the evidence before him when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such device do not conform with the requirements of section 360j(f) of this title and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(F) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that the labeling of such device, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(G) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that such device is not shown to conform in all respects to a performance standard which is in effect under section 360d of this title compliance with which was a condition to approval of the application and that there is a lack of adequate information to justify the deviation from such standard.

(2) The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such withdrawal, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g) of this section.

(f) Product development protocol

(1) In the case of a class III device which is required to have an approval of an application submitted under subsection (c) of this section, such device shall be considered as having such an approval if a notice of completion of testing conducted in accordance with a product development protocol approved under paragraph (4) has been declared completed under paragraph (6).

(2) Any person may submit to the Secretary a proposed product development protocol with respect to a device. Such a protocol shall be accompanied by data supporting it. If, within thirty days of the receipt of such a protocol, the Secretary determines that it appears to be appropriate to apply the requirements of this subsection to the device with respect to which the protocol is submitted, he shall refer the proposed protocol to the appropriate panel under section 360c of this title for its recommendation respecting approval of the protocol.

(3) A proposed product development protocol for a device may be approved only if—

(A) the Secretary determines that it is appropriate to apply the requirements of this subsection to the device in lieu of the requirement of approval of an application submitted under subsection (c) of this section; and

(B) the Secretary determines that the proposed protocol provides—

(i) a description of the device and the changes which may be made in the device,

(ii) a description of the preclinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the commencement of clinical trials of the device, and (II) any permissible variations in preclinical trials and the results therefrom,

(iii) a description of the clinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the filing of a notice of completion of the requirements of the protocol, and (II) any permissible variations in such trials and the results therefrom,

(iv) a description of the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, and,

when relevant, packing and installation of the device,

(v) an identifying reference to any performance standard under section 360d of this title to be applicable to any aspect of such device,

(vi) if appropriate, specimens of the labeling proposed to be used for such device,

(vii) such other information relevant to the subject matter of the protocol as the Secretary, with the concurrence of the appropriate panel or panels under section 360c of this title, may require, and

(viii) a requirement for submission of progress reports and, when completed, records of the trials conducted under the protocol which records are adequate to show compliance with the protocol.

(4) The Secretary shall approve or disapprove a proposed product development protocol submitted under paragraph (2) within one hundred and twenty days of its receipt unless an additional period is agreed upon by the Secretary and the person who submitted the protocol. Approval of a protocol or denial of approval of a protocol is final agency action subject to judicial review under chapter 7 of title 5.

(5) At any time after a product development protocol for a device has been approved pursuant to paragraph (4), the person for whom the protocol was approved may submit a notice of completion—

(A) stating (i) his determination that the requirements of the protocol have been fulfilled and that, to the best of his knowledge, there is no reason bearing on safety or effectiveness why the notice of completion should not become effective, and (ii) the data and other information upon which such determination was made, and

(B) setting forth the results of the trials required by the protocol and all the information required by subsection (c)(1) of this section.

(6)(A) The Secretary may, after providing the person who has an approved protocol and opportunity for an informal hearing and at any time prior to receipt of notice of completion of such protocol, issue a final order to revoke such protocol if he finds that—

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ so substantially from the results required by the protocol that further trials cannot be justified, or

(iii) the results of the trials conducted under the protocol or available new information do not demonstrate that the device tested under the protocol does not present an unreasonable risk to health and safety.

(B) After the receipt of a notice of completion of an approved protocol the Secretary shall, within the ninety-day period beginning on the date such notice is received, by order either declare the protocol completed or declare it not completed. An order declaring a protocol not completed may take effect only after the Secretary has provided the person who has the protocol opportunity for an informal hearing on the order. Such an order may be issued only if the Secretary finds—

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ substantially from the results required by the protocol, or

(iii) there is a lack of a showing of reasonable assurance of the safety and effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

(C) A final order issued under subparagraph (A) or (B) shall be in writing and shall contain the reasons to support the conclusions thereof.

(7) At any time after a notice of completion has become effective, the Secretary may issue an order (after due notice and opportunity for an informal hearing to the person for whom the notice is effective) revoking the approval of a device provided by a notice of completion which has become effective as provided in subparagraph (B) if he finds that any of the grounds listed in subparagraphs (A) through (G) of subsection (e)(1) of this section apply. Each reference in such subparagraphs to an application shall be considered for purposes of this paragraph as a reference to a protocol and the notice of completion of such protocol, and each reference to the time when an application was approved shall be considered for purposes of this paragraph as a reference to the time when a notice of completion took effect.

(8) A person who has an approved protocol subject to an order issued under paragraph (6)(A) revoking such protocol, a person who has an approved protocol with respect to which an order under paragraph (6)(B) was issued declaring that the protocol had not been completed, or a person subject to an order issued under paragraph (7) revoking the approval of a device may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such order, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g) of this section.

(g) Review

(1) Upon petition for review of—

(A) an order under subsection (d) of this section approving or denying approval of an application or an order under subsection (e) of this section withdrawing approval of an application, or

(B) an order under subsection (f)(6)(A) of this section revoking an approved protocol, under subsection (f)(6)(B) of this section declaring that an approved protocol has not been completed, or under subsection (f)(7) of this section revoking the approval of a device,

the Secretary shall, unless he finds the petition to be without good cause or unless a petition for review of such order has been submitted under paragraph (2), hold a hearing, in accordance with section 554 of title 5, on the order. The panel or panels which considered the application, protocol, or device subject to such order shall designate a member to appear and testify at any such hearing upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this requirement does

not preclude any other member of the panel or panels from appearing and testifying at any such hearing. Upon completion of such hearing and after considering the record established in such hearing, the Secretary shall issue an order either affirming the order subject to the hearing or reversing such order and, as appropriate, approving or denying approval of the application, reinstating the application's approval, approving the protocol, or placing in effect a notice of completion.

(2)(A) Upon petition for review of—

(i) an order under subsection (d) of this section approving or denying approval of an application or an order under subsection (e) of this section withdrawing approval of an application, or

(ii) an order under subsection (f)(6)(A) of this section revoking an approved protocol, under subsection (f)(6)(B) of this section declaring that an approved protocol has not been completed, or under subsection (f)(7) of this section revoking the approval of a device,

the Secretary shall refer the application or protocol subject to the order and the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order. The advisory committee shall, after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report shall be promptly supplied by the Secretary to any person who petitioned for such referral to the advisory committee.

(B) The Secretary shall establish advisory committees (which may not be panels under section 360c of this title) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional backgrounds, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter. Members of an advisory committee (other than officers or employees of the United States), while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent for grade GS-18 of the General Schedule for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government service employed intermittently. The Secretary shall designate the chairman of an advisory committee from its members. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

(C) The Secretary shall make public the report and recommendation made by an advisory committee with respect to an application and shall by order, stating the reasons therefor, either affirm the order referred to the advisory committee or reverse such order and, if appropriate, approve or deny approval of the application, reinstate the application's approval, approve the protocol, or place in effect a notice of completion.

(h) Service of orders

Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary, or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last known address in the records of the Secretary.

(June 25, 1938, ch. 675, § 515, as added May 28, 1976, Pub. L. 94-295, § 2, 90 Stat. 552.)

REFERENCES IN TEXT

The General Schedule, referred to in subsec. (g)(2)(B), is set out under section 5332 of Title 5, Government Organization and Employees.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of two year period following Jan. 5, 1973, and advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of two year period beginning on the date of their establishment, unless in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such two year period, or in the case of a committee established by Congress, its duration is otherwise provided by law, see section 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 351, 360, 360c, 360g, 360j, 381 of this title.

§ 360f. Banned devices

(a) General rule

Whenever the Secretary finds, on the basis of all available data and information and after consultation with the appropriate panel or panels under section 360c of this title, that—

(1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and

(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;

he may initiate a proceeding to promulgate a regulation to make such device a banned device. The Secretary shall afford all interested persons opportunity for an informal hearing on a regulation proposed under this subsection.

(b) Special effective date

The Secretary may declare a proposed regulation under subsection (a) of this section to be effective upon its publication in the Federal Register and until the effective date of any final action taken respecting such regulation if (1) he determines, on the basis of all available data and information, that the deception or risk of illness or injury associated with the use of the device which is subject to the regulation presents an unreasonable, direct, and substantial danger to the health of individuals, and (2) before the date of the publication of such regulation, the Secretary notifies the manufacturer of such device that such regulation is to be made so effective. If the Secretary makes a proposed regulation so effective, he shall, as expeditiously as possible, give interested persons prompt notice of his action under this subsection, provide reasonable opportunity for an informal hearing on the proposed regulation, and either affirm, modify, or revoke such proposed regulation.

(June 25, 1938, ch. 675, § 516, as added May 28, 1976, Pub. L. 94-295, § 2, 90 Stat. 560.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 360c, 360e, 360g, 360j, 381 of this title.

§ 360g. Judicial review

(a) Petition; record

Not later than thirty days after—

(1) the promulgation of a regulation under section 360c of this title classifying a device in class I or changing the classification of a device to class I or an order under subsection (f)(2) of such section reclassifying a device or denying a petition for reclassification of a device,

(2) the promulgation of a regulation under section 360d of this title establishing, amending, or revoking a performance standard for a device,

(3) the issuance of an order under section 360d(b)(2) or 360e(b)(2)(B) of this title denying a request for reclassification of a device,

(4) the promulgation of a regulation under paragraph (3) of section 360e(b) of this title requiring a device to have an approval of a premarket application, a regulation under paragraph (4) of that section amending or revoking a regulation under paragraph (3), or an order pursuant to section 360e(g)(1) or 360e(g)(2)(C) of this title,

(5) the promulgation of a regulation under section 360f of this title (other than a proposed regulation made effective under subsection (b) of such section upon the regulation's publication) making a device a banned device,

(6) the issuance of an order under section 360j(f)(2) of this title, or

(7) an order under section 360j(g)(4) of this title disapproving an application for an exemption of a device for investigational use or an order under section 360j(g)(5) of this title withdrawing such an exemption for a device,

any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial review of such regulation or order. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based his regulation or order as provided in section 2112 of title 28. For purposes of this section, the term "record" means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to such regulation or order, proceedings of any panel or advisory committee with respect to such regulation or order, any hearing held with respect to such regulation or order, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

(b) Additional data, views, and arguments

If the petitioner applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceedings before the Secretary, the court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions. The Secretary may modify his findings, or make new findings by reason of the additional data, views, or arguments so taken and shall file with the court such modified or new findings, and his recommendation, if any, for the modification or setting aside of the regulation or order being reviewed, with the return of such additional data, views, or arguments.

(c) Standard for review

Upon the filing of the petition under subsection (a) of this section for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5 and to grant appropriate relief, including interim relief, as provided in such chapter. A regulation described in paragraph (2) or (5) of subsection (a) of this section and an order issued after the review provided by section 360e(g) of this title shall not be affirmed if it is found to be unsupported by substantial evidence on the record taken as a whole.

(d) Finality of judgments

The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28.

(e) Remedies

The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law.

(f) Statement of reasons

To facilitate judicial review under this section or under any other provision of law of a regulation or order issued under section 360c, 360d, 360e, 360f, 360h, 360i, 360j, or 360k of this title each such regulation or order shall contain a statement of the reasons for its issuance and the basis, in the record of the proceedings held in connection with its issuance, for its issuance.

(June 25, 1938, ch. 675, § 517, as added May 28, 1976, Pub. L. 94-295, § 2, 90 Stat. 560.)

§ 360h. Notification and other remedies

(a) Notification

If the Secretary determines that—

(1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk. An order under this subsection shall require that the individuals subject to the risk with respect to which the order is to be issued be included in the persons to be notified of the risk unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notification. If the Secretary makes such a determination with respect to such individuals, the order shall require that the health professionals who prescribe or use the device provide for the notification of the individuals whom the health professionals treated with the device of the risk presented by the device and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

(b) Repair, replacement, or refund

(1)(A) If, after affording opportunity for an informal hearing, the Secretary determines that—

(i) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health,

(ii) there are reasonable grounds to believe that the device was not properly designed and manufactured with reference to the state of the art as it existed at the time of its design and manufacture,

(iii) there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a manufacturer, importer, distributor, or retailer of the device to exercise due care in the installation, maintenance, repair, or use of the device, and

(iv) the notification authorized by subsection (a) of this section would not by itself be sufficient to eliminate the unreasonable risk and action described in paragraph (2) of this subsection is necessary to eliminate such risk,

the Secretary may order the manufacturer, importer, or any distributor of such device, or any combination of such persons, to submit to him within a reasonable time a plan for taking one or more of the actions described in paragraph (2). An order issued under the preceding sentence which is directed to more than one person shall specify which person may decide which action shall be taken under such plan and the person specified shall be the person who the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears such responsibility or the Secretary determines that the protection of the public health requires that such decision be made by a person (including a device user or health professional) other than the person he determines bears such responsibility.

(B) The Secretary shall approve a plan submitted pursuant to an order issued under subparagraph (A) unless he determines (after affording opportunity for an informal hearing) that the action or actions to be taken under the plan or the manner in which such action or actions are to be taken under the plan will not assure that the unreasonable risk with respect to which such order was issued will be eliminated. If the Secretary disapproves a plan, he shall order a revised plan to be submitted to him within a reasonable time. If the Secretary determines (after affording opportunity for an informal hearing) that the revised plan is unsatisfactory or if no revised plan or no initial plan has been submitted to the Secretary within the prescribed time, the Secretary shall (i) prescribe a plan to be carried out by the person or persons to whom the order issued under subparagraph (A) was directed, or (ii) after affording an opportunity for an informal hearing, by order prescribe a plan to be carried out by a person who is a manufacturer, importer, distributor, or retailer of the device with respect to which the order was issued but to whom the order under subparagraph (A) was not directed.

(2) The actions which may be taken under a plan submitted under an order issued under paragraph (1) are as follows:

(A) To repair the device so that it does not present the unreasonable risk of substantial harm with respect to which the order under paragraph (1) was issued.

(B) To replace the device with a like or equivalent device which is in conformity with all applicable requirements of this chapter.

(C) To refund the purchase price of the device (less a reasonable allowance for use if

such device has been in the possession of the device user for one year or more—

(i) at the time of notification ordered under subsection (a) of this section, or

(ii) at the time the device user receives actual notice of the unreasonable risk with respect to which the order was issued under paragraph (1),

whichever first occurs).

(3) No charge shall be made to any person (other than a manufacturer, importer, distributor or retailer) for availing himself of any remedy, described in paragraph (2) and provided under an order issued under paragraph (1), and the person subject to the order shall reimburse each person (other than a manufacturer, importer, distributor, or retailer) who is entitled to such a remedy for any reasonable and foreseeable expenses actually incurred by such person in availing himself of such remedy.

(c) Reimbursement

An order issued under subsection (b) of this section with respect to a device may require any person who is a manufacturer, importer, distributor, or retailer of the device to reimburse any other person who is a manufacturer, importer, distributor, or retailer of such device for such other person's expenses actually incurred in connection with carrying out the order if the Secretary determines such reimbursement is required for the protection of the public health. Any such requirement shall not affect any rights or obligations under any contract to which the person receiving reimbursement or the person making such reimbursement is a party.

(d) Effect on other liability

Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

(June 25, 1938, ch. 675, § 518, as added May 28, 1976, Pub. L. 94-295, § 2, 90 Stat. 562.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352, 360c, 360g, 360j of this title.

§ 360i. Records and reports on devices

(a) General rule

Every person who is a manufacturer, importer, or distributor of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed under the preceding sentence—

(1) shall not impose requirements unduly burdensome to a device manufacturer, importer, or distributor taking into account his cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;

(2) which prescribe the procedure for making requests for reports or information shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

(3) which require submission of a report or information to the Secretary shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information;

(4) may not require that the identity of any patient be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under this chapter; and

(5) may not require a manufacturer, importer, or distributor of a class I device to—

(A) maintain for such a device records respecting information not in the possession of the manufacturer, importer, or distributor, or

(B) to submit for such a device to the Secretary any report or information—

(i) not in the possession of the manufacturer, importer, or distributor, or

(ii) on a periodic basis,

unless such report or information is necessary to determine if the device should be reclassified or if the device is adulterated or misbranded.

In prescribing such regulations, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (4) of this subsection continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(b) Persons exempt

Subsection (a) of this section shall not apply to—

(1) any practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of his professional practice;

(2) any person who manufactures or imports devices intended for use in humans solely for such person's use in research or teaching and not for sale (including any person who uses a device under an exemption granted under section 360j(g) of this title); and

(3) any other class of persons as the Secretary may by regulation exempt from subsection (a) of this section upon a finding that compliance with the requirements of such subsection by such class with respect to a device is not necessary to (A) assure that a device is not adulterated or misbranded or (B) otherwise to assure its safety and effectiveness.

(June 25, 1938, ch. 675, § 519, as added May 28, 1976, Pub. L. 94-295, § 2, 90 Stat. 564.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352, 360c, 360e, 360g, 360j, 374 of this title.

§ 360j. General provisions respecting control of devices intended for human use

(a) General rule

Any requirement authorized by or under section 351, 352, 360, or 360i of this title applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 360c, 360d, or 360e of this title or under subsection (g) of this section, and any requirement established by or under section 351, 352, 360, or 360i of this title which is inconsistent with a requirement imposed on such device under section 360d or 360e of this title or under subsection (g) of this section shall not apply to such device.

(b) Custom devices

Sections 360d and 360e of this title do not apply to any device which, in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing) necessarily deviates from an otherwise applicable performance standard or requirement prescribed by or under section 360e of this title if (1) the device is not generally available in finished form for purchase or for dispensing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and (2) such device—

(i) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated) and is to be made in a specific form for such patient, or

(ii) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated), and

(B) is not generally available to or generally used by other physicians or dentists (or other specially qualified persons so designated).

(c) Trade secrets

Any information reported to or otherwise obtained by the Secretary or his representative under section 360c, 360d, 360e, 360f, 360h, 360i, or 374 of this title or under subsection (f) or (g) of this section which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device under section 360c of this title from class III to class II or as the basis for the establishment or amendment of a performance standard under section 360d of this title for a device reclassified from class III to class II, except that such information may be disclosed to other officers or employees concerned with carrying out this chapter or when relevant in any proceeding under this chapter (other than section 360c or 360d of this title).

(d) Notices and findings

Each notice of proposed rulemaking under section 360c, 360d, 360e, 360f, 360h, or 360i of this title, or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings is based, and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefor) orally or in writing, which period shall be at least sixty days but may not exceed ninety days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefor.

(e) Restricted devices

(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialities or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

(f) Good manufacturing practice requirements

(1)(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this chapter.

(B) Before the Secretary may promulgate any regulation under subparagraph (A) he shall—

(i) afford the advisory committee established under paragraph (3) an opportunity to

submit recommendations to him with respect to the regulation proposed to be promulgated, and

(ii) afford opportunity for an oral hearing.

The Secretary shall provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A).

(2)(A) Any person subject to any requirement prescribed by regulations under paragraph (1) may petition the Secretary for an exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as he shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this chapter,

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, facilities, and controls prescribed by the requirement, and

(iii) contain such other information as the Secretary shall prescribe.

(B) The Secretary may refer to the advisory committee established under paragraph (3) any petition submitted under subparagraph (A). The advisory committee shall report its recommendations to the Secretary with respect to a petition referred to it within sixty days of the date of the petition's referral. Within sixty days after—

(i) the date the petition was submitted to the Secretary under subparagraph (A), or

(ii) if the petition was referred to an advisory committee, the expiration of the sixty-day period beginning on the date the petition was referred to the advisory committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

(C) The Secretary may approve—

(i) a petition for an exemption for a device from a requirement if he determines that compliance with such requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this chapter, and

(ii) a petition for a variance for a device from a requirement if he determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to assure that the device will be safe and effective and otherwise in compliance with this chapter.

An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of the device to be granted the variance under the petition as may be necessary to assure that the device will be safe and effective and otherwise in compliance with this chapter.

(D) After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) The Secretary shall establish an advisory committee for the purpose of advising and making recommendations to him with respect to regulations proposed to be promulgated under paragraph (1)(A) and the approval or disapproval of petitions submitted under paragraph (2). The advisory committee shall be composed of nine members as follows:

(A) Three of the members shall be appointed from persons who are officers or employees of any State or local government or of the Federal Government.

(B) Two of the members shall be appointed from persons who are representative of interests of the device manufacturing industry; two of the members shall be appointed from persons who are representative of the interests of physicians and other health professionals; and two of the members shall be representative of the interests of the general public.

Members of the advisory committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government service employed intermittently. The Secretary shall designate one of the members of the advisory committee to serve as its chairman. The Secretary shall furnish the advisory committee with clerical and other assistance. Section 14 of the Federal Advisory Committee Act shall not apply with respect to the duration of the advisory committee established under this paragraph.

(g) Exemption for devices for investigational use

(1) It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on May 28, 1976, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 352, 360, 360d, 360e, 360f, 360i, or 376 of this title or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training

and experience to investigate the safety and effectiveness of such devices.

(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device subject to the exemption during testing conducted in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data to obtain approval for the commercial distribution of such device.

(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption—

(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing—

(i) to the local institutional review committee which has been established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

(ii) to the Secretary, if—

(I) no such committee exists, or

(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the plan for such testing has been approved by such committee),

for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by a local institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except where subject to such conditions as the Secretary may prescribe, the investigator conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative.

The determination required by subparagraph (D) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

(4)(A) An application, submitted in accordance with the procedures prescribed by regulations under paragraph (2), for an exemption for a device (other than an exemption from section 360f of this title) shall be deemed approved on the thirtieth day after the submission of the application to the Secretary unless on or before such day the Secretary by order disapproves the application and notifies the applicant of the disapproval of the application.

(B) The Secretary may disapprove an application only if he finds that the investigation with respect to which the application is submitted does not conform to procedures and conditions prescribed under regulations under paragraph (2). Such a notification shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application and afford the applicant opportunity for an informal hearing on the disapproval order.

(5) The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the conditions applicable to the device under this subsection for such exemption are not met. Such an order may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health.

(h) Release of information respecting safety and effectiveness

(1) The Secretary shall promulgate regulations under which a detailed summary of information respecting the safety and effectiveness

of a device which information was submitted to the Secretary and which was the basis for—

(A) an order under section 360e(d)(1)(A) of this title approving an application for premarket approval for the device or denying approval of such an application or an order under section 360e(e) of this title withdrawing approval of such an application for the device,

(B) an order under section 360e(f)(6)(A) of this title revoking an approved protocol for the device, an order under section 360e(f)(6)(B) of this title declaring a protocol for the device completed or not completed, or an order under section 360e(f)(7) of this title revoking the approval of the device, or

(C) an order approving an application under subsection (g) of this section for an exemption for the device from section 360f of this title or an order disapproving, or withdrawing approval of, an application for an exemption under such subsection for the device,

shall be made available to the public upon issuance of the order. Summaries of information made available pursuant to this paragraph respecting a device shall include information respecting any adverse effects on health of the device.

(2) The Secretary shall promulgate regulations under which each advisory committee established under section 360e(g)(2)(B) of this title shall make available to the public a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the advisory committee and which was the basis for its recommendation to the Secretary made pursuant to section 360e(g)(2)(A) of this title. A summary of information upon which such a recommendation is based shall be made available pursuant to this paragraph only after the issuance of the order with respect to which the recommendation was made and each summary shall include information respecting any adverse effect on health of the device subject to such order.

(3) Any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) may not be used to establish the safety or effectiveness of another device for purposes of this chapter by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section.

(i) Proceedings of advisory panels and committees

Each panel under section 360c of this title and each advisory committee established under section 360d(g)(5)(B) or 360e(g) of this title or under subsection (f) of this section shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made pursuant to this subsection information which under subsection (c) of this section is to be considered confidential.

(j) Traceability

No regulation under this chapter may impose on a type or class of device requirements for the traceability of such type or class of device unless such requirements are necessary to assure the protection of the public health.

(k) Research and development

The Secretary may enter into contracts for research, testing, and demonstrations respecting devices and may obtain devices for research, testing, and demonstration purposes without regard to sections 529 of title 31 and 5 of title 41.

(*l*) Transitional provisions for devices considered as new drugs or antibiotic drugs

(1) Any device intended for human use—

(A) for which on May 28, 1976 (hereinafter in this subsection referred to as the "enactment date") an approval of an application submitted under section 355(b) of this title was in effect;

(B) for which such an application was filed on or before the enactment date and with respect to which application no order of approval or refusing to approve had been issued on such date under subsection (c) or (d) of such section;

(C) for which on the enactment date an exemption under subsection (i) of such section was in effect;

(D) which is within a type of device described in subparagraph (A), (B), or (C) and is substantially equivalent to another device within that type;

(E) which the Secretary in a notice published in the Federal Register before the enactment date has declared to be a new drug subject to section 355 of this title; or

(F) with respect to which on the enactment date an action is pending in a United States court under section 332, 333, or 334 of this title for an alleged violation of a provision of section 331 of this title which enforces a requirement of section 355 of this title or for an alleged violation of section 355(a) of this title,

is classified in class III unless the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

(2) The manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Except as provided in paragraph (3)(D)(ii), within one hundred and eighty days after the filing of a petition under this paragraph and after affording the petitioner an opportunity for an informal hearing, the Secretary shall, after consultation with the appropriate panel under section 360c of this title, by order either deny the petition or order the classification, in accordance with the criteria prescribed by section 360c(a)(1)(A) of this title or 360c(a)(1)(B) of this title, of the device in class I or class II.

(3)(A) In the case of a device which is described in paragraph (1)(A) and which is in class III—

(i) such device shall on the enactment date be considered a device with an approved application under section 360e of this title, and

(ii) the requirements applicable to such device before the enactment date under sec-

tion 355 of this title shall continue to apply to such device until changed by the Secretary as authorized by this chapter.

(B) In the case of a device which is described in paragraph (1)(B) and which is in class III, an application for such device shall be considered as having been filed under section 360e of this title on the enactment date. The period in which the Secretary shall act on such application in accordance with section 360e(d)(1) of this title shall be one hundred and eighty days from the enactment date (or such greater period as the Secretary and the applicant may agree upon after the Secretary has made the finding required by section 360e(d)(1)(B)(i) of this title) less the number of days in the period beginning on the date an application for such device was filed under section 355 of this title and ending on the enactment date. After the expiration of such period such device is required, unless exempt under subsection (g) of this section, to have in effect an approved application under section 360e of this title.

(C) A device which is described in paragraph (1)(C) and which is in class III shall be considered a new drug until the expiration of the ninety-day period beginning on the date of the promulgation of regulations under subsection (g) of this section. After the expiration of such period such device is required, unless exempt under subsection (g) of this section, to have in effect an approved application under section 360e of this title.

(D)(i) Except as provided in clauses (ii) and (iii), a device which is described in subparagraph (D), (E), or (F) of paragraph (1) and which is in class III is required, unless exempt under subsection (g) of this section, to have on and after sixty days after the enactment date in effect an approved application under section 360e of this title.

(ii) If—

(I) a petition is filed under paragraph (2) for a device described in subparagraph (D), (E), or (F) of paragraph (1), or

(II) an application for premarket approval is filed under section 360e of this title for such a device,

within the sixty-day period beginning on the enactment date (or within such greater period as the Secretary, after making the finding required under section 360e(d)(1)(B) of this title, and the petitioner or applicant may agree upon), the Secretary shall act on such petition or application in accordance with paragraph (2) or section 360e of this title except that the period within which the Secretary must act on the petition or application shall be within the one hundred and twenty-day period beginning on the date the petition or application is filed. If such a petition or application is filed within such sixty-day (or greater) period, clause (i) of this subparagraph shall not apply to such device before the expiration of such one hundred and twenty-day period, or if such petition is denied or such application is denied approval, before the date of such denial, whichever occurs first.

(iii) In the case of a device which is described in subparagraph (E) of paragraph (1), which the Secretary in a notice published in the Federal Register after March 31, 1976, declared to be a new drug subject to section 355 of this title, and which is in class III—

(I) the device shall, after eighteen months after the enactment date, have in effect an approved application under section 360e of this title unless exempt under subsection (g) of this section, and

(II) the Secretary may, during the period beginning one hundred and eighty days after the enactment date and ending eighteen months after such date, restrict the use of the device to investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of such device, and to investigational use in accordance with the requirements applicable under regulations under subsection (g) of this section to investigational use of devices granted an exemption under such subsection.

If the requirements under subsection (g) of this section are made applicable to the investigational use of such a device, they shall be made applicable in such a manner that the device shall be made reasonably available to physicians meeting appropriate qualifications prescribed by the Secretary.

(4) Any device intended for human use which on the enactment date was subject to the requirements of section 357 of this title shall be subject to such requirements as follows:

(A) In the case of such a device which is classified into class I, such requirements shall apply to such device until the effective date of the regulation classifying the device into such class.

(B) In the case of such a device which is classified into class II, such requirements shall apply to such device until the effective date of a performance standard applicable to the device under section 360d of this title.

(C) In the case of such a device which is classified into class III, such requirements shall apply to such device until the date on which the device is required to have in effect an approved application under section 360e of this title.

(June 25, 1938, ch. 675, § 520, as added May 28, 1976, Pub. L. 94-295, § 2, 90 Stat. 565.)

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (f)(3), is Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770, which is set out in the Appendix to Title 5, Government Organization and Employees.

The General Schedule, referred to in subsec. (f)(3), is set out under section 5332 of Title 5.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 351, 352, 360c, 360d, 360e, 360g, 360i, 374, 381 of this title.

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

(June 25, 1938, ch. 675, § 521, as added May 28, 1976, Pub. L. 94-295, § 2, 90 Stat. 574.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360g of this title.

SUBCHAPTER VI—COSMETICS

§ 361. Adulterated cosmetics

A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: *Provided*, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this subsection and subsection (e) of this section the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 376(a) of this title.

(June 25, 1938, ch. 675, § 601, 52 Stat. 1054; July 12, 1960, Pub. L. 86-618, title I, § 102(c)(1), 74 Stat. 398.)

AMENDMENTS

1960—Subsec. (e). Pub. L. 86-618 substituted "and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 376(a) of this title" for "and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 364 of this title".

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective, subject to the provisions of section 203 of Pub. L. 86-618, on July 12, 1960, see section 202 of Pub. L. 86-618, set out as an Effective Date of 1960 Amendment note under section 376 of this title.

EFFECTIVE DATE; POSTPONEMENT

Subsec. (e) of this section effective Jan. 1, 1940, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date note under section 301 of this title.

EFFECTIVE DATE

Section effective twelve months after June 25, 1938, except subsec. (a), which, with certain exceptions, became effective on June 25, 1938, see section 902(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 334, 376 of this title.

§ 362. Misbranded cosmetics

A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this subsection reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 376 of this title. This subsection shall not apply to packages of color additives which, with respect to

their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 361(a) of this title).

(f) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of title 15.

(June 25, 1938, ch. 675, § 602, 52 Stat. 1054; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; July 12, 1960, Pub. L. 86-618, title I, § 102(c)(2), 74 Stat. 398; Dec. 30, 1970, Pub. L. 91-601, § 7(f), 84 Stat. 1673.)

AMENDMENTS

1970—Subsec. (f). Pub. L. 91-601 added subsec. (f).
1960—Subsec. (e). Pub. L. 86-618 added subsec. (e).

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91-601 effective Dec. 30, 1970, and regulations establishing special packaging standards effective no sooner than 180 days or later than one year from date regulations are final, or an earlier date published in Federal Register, see section 9 of Pub. L. 91-601, set out as an Effective Date note under section 1471 of Title 15, Commerce and Trade.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective, subject to the provisions of section 203 of Pub. L. 86-618, on July 12, 1960, see section 202 of Pub. L. 86-618, set out as an Effective Date of 1960 Amendment note under section 376 of this title.

EFFECTIVE DATE; POSTPONEMENT

Subsec. (b) of this section effective Jan. 1, 1940, and such subsection effective July 1, 1940, as provided by regulations for certain lithographed labeling and containers bearing certain labeling, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date note under section 301 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 321 of this title.

§ 363. Regulations making exemptions

The Secretary shall promulgate regulations exempting from any labeling requirement of this chapter cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

(June 25, 1938, ch. 675, § 603, 52 Stat. 1054; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

See, also, note under section 321 of this title.

§ 364. Repealed. Pub. L. 86-618, title I, § 103(a)(3), July 12, 1960, 74 Stat. 398

Section, act June 25, 1938, ch. 675, § 604, 52 Stat. 1055, required the Secretary to promulgate regulations for the listing of coal-tar colors for cosmetics and is covered by section 376 of this title.

EFFECTIVE DATE OF REPEAL

Repeal of section effective, subject to the provisions of section 203 of Pub. L. 86-618, on July 12, 1960, see section 202 of Pub. L. 86-618, set out as an Effective Date of 1960 Amendment note under section 376 of this title.

SUBCHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

§ 371. Regulations and hearings

(a) Authority to promulgate regulations

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

(b) Regulations for imports and exports

The Secretary of the Treasury and the Secretary of Health, Education, and Welfare shall jointly prescribe regulations for the efficient enforcement of the provisions of section 381 of this title, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health, Education, and Welfare shall determine.

(c) Conduct of hearings

Hearings authorized or required by this chapter shall be conducted by the Secretary of Health, Education, and Welfare or such officer or employee as he may designate for the purpose.

(d) Effectiveness of definitions and standards of identity

The definitions and standards of identity promulgated in accordance with the provisions of this chapter shall be effective for the purposes of the enforcement of this chapter, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e) Procedure for establishment

(1) Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f) Review of order

(1) In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28.

(2) If the petitioner applies to the court for leave to adduce additonal evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additonal evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in additon to and not in substitution for any other remedies provided by law.

(g) Copies of records of hearings

A certified copy of the transcript of the record and proceedings under subsection (e) of this section shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this chapter, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f) of this section.

(June 25, 1938, ch. 675, § 701, 52 Stat. 1055; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; June 25, 1948, ch. 646, § 32, 62 Stat. 991; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Apr. 15, 1954, ch. 143, § 2, 68 Stat. 55; Aug. 1, 1956, ch. 861, § 2, 70 Stat. 919; Aug. 28, 1958, Pub. L. 85-791, § 21, 72 Stat. 948; July 12, 1960, Pub. L. 86-618, title I, § 103(a)(4), 74 Stat. 398.)

CODIFICATION

In subsec. (f)(4), "section 1254 of title 28" was substituted for "sections 239 and 240 of the Judicial Code, as amended" on authority of act June 25, 1948, ch. 646, 62 Stat. 869, the first section of which enacted Title 28, Judiciary and Judicial Procedure.

AMENDMENTS

1960—Subsec. (e). Pub. L. 86-618 substituted "section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h), of this title" for "section 341, 343(j), 344(a), 346(a) or (b), 351(b), 352(d) or (h), 354 or 364 of this title".

1958—Subsec. (f)(1). Pub. L. 85-791, § 21(a), substituted provisions requiring transmission of a copy of the petition by clerk to Secretary, and filing of the record by Secretary, for provisions which permitted service of summons and petition any place in United States and required Secretary to certify and file transcript of the proceedings and record upon service.

Subsec. (f)(3). Pub. L. 85-791, § 21(b), inserted "Upon the filing of the petition referred to in paragraph (1) of this subsection".

1956—Subsec. (e). Act Aug. 1, 1956, simplified the procedures governing the prescribing of regulations under certain provisions of this chapter.

1954—Subsec. (e). Act Apr. 15, 1954, struck out the reference to section 341 of this title, preceding "343(j)", such section 341 now containing its own provisions with respect to hearings regarding the establishment of food standards.

CHANGE OF NAME

The Circuit Court of Appeals of the United States was changed to the United States court of appeals by act June 25, 1948, eff. Sept. 1, 1948.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective, subject to the provisions of section 203 of Pub. L. 86-618, on July 12, 1960, see section 202 of Pub. L. 86-618, set out as an Effective Date of 1960 Amendment note under section 376 of this title.

SAVINGS PROVISIONS

Savings clause of act Aug. 1, 1956, which amended subsec. (e) of this section, see Savings Provisions note under section 341 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

HEARINGS PENDING ON APRIL 15, 1954, WITH RESPECT TO FOOD STANDARDS

Provisions of this chapter in effect prior to Apr. 15, 1954, as applicable with respect to hearings begun prior to such date under subsection (e) of this section, regarding food standards, see Savings Provisions note under section 341 of this title.

CROSS REFERENCES

Pesticide chemical regulations, see section 346a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 346a, 352, 356, 357, 376 of this title; title 15 sections 1261, 1262, 1455, 1474.

§ 372. Examinations and investigations

(a) Authority to conduct

The Secretary is authorized to conduct examinations and investigations for the purposes of this chapter through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department. In the case of food packed in the Commonwealth of Puerto Rico or a Territory the Secretary shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions of this chapter, the facilities at his disposal will permit of such inspection. For the purposes of this subsection the term "United States" means the States and the District of Columbia.

(b) Availability to owner of part of analysis samples

Where a sample of a food, drug, or cosmetic is collected for analysis under this chapter the Secretary shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this chapter.

(c) Records of other departments and agencies

For purposes of enforcement of this chapter, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Department duly authorized by the Secretary to make such inspection.

(d) Information on patents for drugs

The Secretary is authorized and directed, upon request from the Commissioner of Patents and Trademarks, to furnish full and complete information with respect to such questions relating to drugs as the Commissioner may submit concerning any patent application. The Secretary is further authorized, upon receipt of any such request, to conduct or cause to be conducted, such research as may be required.

(e) Powers of enforcement personnel

Any officer or employee of the Department designated by the Secretary to conduct examinations, investigations, or inspections under this chapter relating to counterfeit drugs may, when so authorized by the Secretary—

(1) carry firearms;

(2) execute and serve search warrants and arrest warrants;

(3) execute seizure by process issued pursuant to libel under section 334 of this title;

(4) make arrests without warrant for offenses under this chapter with respect to such drugs if the offense is committed in his presence or, in the case of a felony, if he has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

(5) make, prior to the institution of libel proceedings under section 334(a)(2) of this title, seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or he has reasonable grounds to believe that they are, subject to seizure and condemnation under such section 334(a)(2). In the event of seizure pursuant to this paragraph (5), libel proceedings under section 334(a)(2) of this title shall be instituted promptly and the property seized be placed under the jurisdiction of the court.

(June 25, 1938, ch. 675, § 702, 52 Stat. 1056; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Oct. 10, 1962, Pub. L. 87-781, title III, §§ 307(b), 308, 76 Stat. 796; July 15, 1965, Pub. L. 89-74, § 8(a), 79 Stat. 234; Oct. 27, 1970, Pub. L. 91-513, title II, § 701(f), 84 Stat. 1282; Jan. 2, 1975, Pub. L. 93-596, § 3, 88 Stat. 1949.)

AMENDMENTS

1970—Subsec. (e). Pub. L. 91-513 struck out reference to depressant or stimulant drugs.

1965—Subsec. (e). Pub. L. 89-74 added subsec. (e).

1962—Subsec. (a). Pub. L. 87-781, § 307(b), inserted "the Commonwealth of Puerto Rico or" preceding "a Territory the Secretary."

Subsec. (d). Pub. L. 87-781, § 308, added subsec. (d).

CHANGE OF NAME

"Commissioner of Patents" redesignated "Commissioner of Patents and Trademarks", by section 3 of Pub. L. 93-596, Jan. 2, 1975, 88 Stat. 1949, set out as a note under section 1 of Title 35, Patents.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91-513 effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91-513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89-74 effective July 15, 1965, see section 11 of Pub. L. 89-74, set out as an Effective Date of 1965 Amendment note under section 321 of this title.

SAVINGS PROVISIONS

Amendment by Pub. L. 91-513 not to affect or abate any prosecutions for any violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91-513, set out as a Savings Provisions note under section 321 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 321 of this title.

§ 372a. Examination of sea food on request of packer; marking food with results; fees; penalties

The Secretary of Health, Education, and Welfare, upon application of any packer of any sea food for shipment or sale within the jurisdiction of this chapter, may, at his discretion, designate inspectors to examine and inspect such food and the production, packing, and labeling thereof. If on such examination and inspection compliance is found with the provisions of this chapter and regulations promulgated thereunder, the applicant shall be authorized or required to mark the food as provided by regulation to show such compliance. Services under this section shall be rendered only upon payment by the applicant of fees fixed by regulation in such amounts as may be necessary to provide, equip, and maintain an adequate and efficient inspection service. Receipts from such fees shall be covered into the Treasury and shall be available to the Secretary of Health, Education, and Welfare for expenditures incurred in carrying out the purposes of this section, including expenditures for salaries of additional inspectors when necessary to supplement the number of inspectors for whose salaries Congress has appropriated. The Secretary is authorized to promulgate regulations governing the sanitary and other conditions under which the service herein provided shall be granted and maintained, and for otherwise carrying out the purposes of this section. Any person who forges, counterfeits, simulates, or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification devices authorized or required by the provisions of this section or regulations thereunder, shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year or a fine of not less than $1,000 nor more than $5,000, or both such imprisonment and fine.

(June 25, 1938, ch. 675, § 702A, as added June 22, 1934, ch. 712, 48 Stat. 1204, amended Aug. 27, 1935, ch. 739, 49 Stat. 871; June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237, renumbered July 12, 1943, ch. 221, title II, § 1, 57 Stat. 500, and amended 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

CODIFICATION

Section, which formerly was not a provision of the Federal Food, Drug, and Cosmetic Act, originally was section 14a of this title. Section 902(a) of act June 25, 1938, set out as a note under section 301 of this title, provided that the section should remain in force and effect and be applicable to the provisions of this chapter. Act July 12, 1943, renumbered this section as 702A of the Federal Food, Drug, and Cosmetic Act.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

§ 373. Records of interstate shipment

For the purpose of enforcing the provisions of this chapter, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates: *Provided*, That evidence obtained under this section, or any evidence which is directly or indirectly derived from such evidence, shall not be used in a criminal prosecution of the person from whom obtained: *Provided further*, That carriers shall not be subject to the other provisions of this chapter by reason of their receipt, carriage, holding, or delivery of food, drugs, de-

vices, or cosmetics in the usual course of business as carriers.

(June 25, 1938, ch. 675, § 703, 52 Stat. 1057; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Oct. 15, 1970, Pub. L. 91-452, title II, § 230, 84 Stat. 930.)

AMENDMENTS

1970—Pub. L. 91-452 added ", or any evidence which is directly or indirectly derived from such evidence," following "under this section".

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91-452 effective on the sixtieth day following Oct. 15, 1970, see section 260 of Pub. L. 91-452, set out as an Effective Date; Savings Provisions note under section 6001 of Title 18, Crimes and Criminal Procedure.

SAVINGS PROVISIONS

Amendment by Pub. L. 91-452 not to affect any immunity to which any individual is entitled under this section by reason of any testimony given before the sixtieth day following Oct. 15, 1970, see section 260 of Pub. L. 91-452, set out as Effective Date; Savings Provisions note under section 6001 of Title 18, Crimes and Criminal Procedure.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

CROSS REFERENCES

Immunity of witnesses, see section 6001 et seq. of Title 18, Crimes and Criminal Procedure.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 331 of this title.

§ 374. Inspection

(a) Right of agents to enter; scope of inspection; notice; promptness; exclusions

For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials;[1] containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs or restricted devices which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter. No inspection authorized by the preceding sentence shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this chapter), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 355(i) or (j), section 357(d) or (g), section 360i, or 360j(g) of this title, and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 355(j) of this title). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this subsection shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(2) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices, solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs or manufacture or process devices, solely for use in research, teaching, or chemical analysis and not for sale;

(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

(b) Written report to owner; copy to Secretary

Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him

[1] So in original, probably should be a comma.

which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

(c) Receipt for samples taken

If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

(d) Analysis of samples furnished owner

Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

(e) Accessibility of records

Every person required under section 360i or 360j(g) of this title to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records.

(June 25, 1938, ch. 675, § 704, 52 Stat. 1057; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 7, 1953, ch. 350, § 1, 67 Stat. 476; Oct. 10, 1962, Pub. L. 87-781, title II, § 201(a), (b), 76 Stat. 792; May 28, 1976, Pub. L. 94-295, § 6, 90 Stat. 581.)

AMENDMENTS

1976—Subsec. (a). Pub. L. 94-295, § 6(a) to (c), expanded existing provisions to encompass medical devices by adding references to factories, warehouses, establishments, and consulting laboratories in which restricted devices are manufactured, processed, packed, or held, inspections relating to devices, reporting and inspection regulations issued pursuant to sections 360i and 360j(g) of this title, and the manufacture and processing of devices.

Subsec. (e). Pub. L. 94-295, § 6(d), added subsec. (e).

1962—Subsec. (a). Pub. L. 87-781, § 201(a), extended the inspection, where prescription drugs are manufactured, processed, packed, or held, to all things bearing on whether adulterated or misbranded drugs, or any which may not be manufactured, introduced in interstate commerce, or sold or offered for sale under any provision of this chapter, have been or are being manufactured, processed, packed, transported or held in any such place, or otherwise bearing on violation of this chapter, but excluded from such inspection, data concerning finance, sales other than shipment, pricing, personnel other than qualifications of technical and professional personnel, research other than relating to new drugs subject to reporting, provided that the provisions of the second sentence of this subsection shall be inapplicable to pharmacies, practitioners and other persons enumerated in pars. (1) to (4), and eliminated "are held" preceding "after such introduction".

Subsec. (b). Pub. L. 87-781, § 201(b), inserted "consulting laboratory" following "warehouse".

1953—Act Aug. 7, 1953, designated existing provisions as subsec. (a) and amended them by substituting provisions permitting entry and inspection upon presentation of appropriate credentials and a written notice to the owner, operator, or agent in charge for provisions which authorized entry and inspection only after making a request and obtaining permission from the owner, operator, or custodian, and inserting provisions requiring a separate written notice for each inspection but not for each entry made during the period covered by the inspection, and directing that the inspection shall be conducted within reasonable limits, in a reasonable manner and completed with reasonable promptness, and added subsecs. (b) to (d).

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by Pub. L. 87-781 effective Oct. 10, 1962, see section 203 of Pub. L. 87-781 set out as an Effective Date of 1962 Amendment note under section 332 of this title.

AUTHORITY OF SECRETARY PRIOR TO OCTOBER 10, 1962

Section 201(d) of Pub. L. 87-781 provided that: "Nothing in the amendments made by subsections (a) and (b) of this section [to subsecs. (a) and (b) of this section] shall be construed to negate or derogate from any authority of the Secretary existing prior to the enactment of this Act [Oct. 10, 1962]."

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 334, 360, 360e, 360j of this title.

§ 375. Publicity

(a) Reports

The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this chapter, including the nature of the charge and the disposition thereof.

(b) Information regarding certain goods

The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

(June 25, 1938, ch. 675, § 705, 52 Stat. 1057; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to

the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

§ 376. Listing and certification of color additives for foods, drugs, devices, and cosmetics

(a) Unsafe color additives

A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or devices or cosmetics, be deemed unsafe for the purposes of the application of section 342(c), 351(a)(4), or 361(e) of this title, as the case may be, unless—

(1)(A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c) of this section, for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) of this section with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 342(a) of this title if such article is a food, or within the meaning of section 361(a) of this title if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 361(a) of this title). A color additive for use in or on a device shall be subject to this section only if the color additive comes in direct contact with the body of man or other animals for a significant period of time. The Secretary may by regulation designate the uses of color additives in or on devices which are subject to this section.

(b) Listing of colors; regulations; issuance, amendment or repeal; referral to advisory committee; report and recommendations; appointment and compensation of advisory committee

(1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, or devices, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

(2)(A) Such regulations may list any color additive for use generally in or on food, or in or on drugs or devices, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: *Provided, however,* That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term "food additive" because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 321(s) of this title.

(5)(A) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs or devices, or cosmetics because of the use of the additive;

(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug or device, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.

(B) A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secre-

tary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal: *Provided*, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d) of this section) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal.

(C)(i) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order issued in accordance with paragraph (1) of section 371(e) of this title if placed in effect, may request, within the time specified in this subparagraph, that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) of this paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee under subparagraph (D) of this paragraph and shall refer to it, together with all the data before him, such matter arising under subparagraph (B) for study thereof and for a report and recommendations on such matter. A person who has filed a petition or who has requested the referral of a matter to an advisory committee pursuant to this subparagraph (C), as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it. The request for referral under this subparagraph, or the Secretary's referral on his own initiative, may be made at any time before, or within thirty days after, publication of an order of the Secretary acting upon the petition or proposal.

(ii) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the foregoing shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order confirm or modify any order theretofore issued or, if no such prior order has been issued, shall by order act upon the petition or other proposal.

(iii) Where—

(I) by reason of subparagraph (B) of this paragraph, the Secretary has initiated a proposal to remove from listing a color additive previously listed pursuant to this section; and

(II) a request has been made for referral of such proposal to an advisory committee;

the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations to him under clause (ii) of this subparagraph and he has considered such recommendations, unless the Secretary finds that emergency conditions exist necessitating the issuance of an order notwithstanding this clause.

(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. Members of any advisory committee established under this chapter, while attending conferences or meetings of their committees or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary but at rates not exceeding the daily equivalent of the rate specified at the time of such service for grade GS–18 of the General Schedule, including traveltime; and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of title 5 for persons in the Government service employed intermittently. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this chapter or would otherwise result in misbranding or adulteration within the meaning of this chapter.

(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure

that a proposed use of a color additive will be safe, the Secretary—

(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for all the uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety), (A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses; (B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

(c) Certification of colors

The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) of this section and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: *Provided*, That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

(d) Procedure for issuance, amendment, or repeal of regulations

The provisions of section 371(e), (f), and (g) of this title shall, subject to the provisions of subparagraph (c) of subsection (b)(5) of this section, apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsection (b) or (c) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 371(e) of this title) acting upon such proposal shall, in the absence of prior referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petiton) as the Secretary deems necessary to enable him to study and investigate the petition;

(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subparagraph (D) of subsection (b)(5) of this section, shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 556(d) of title 5. The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing;

(3) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 348(f)(2) of this title; and

(4) the scope of judicial review of such order shall be in accordance with the fourth sentence of paragraph (2), and with the provisions of paragraph (3), of section 348(g) of this title.

(e) Fees

The admitting to listing and certification of color additives, in accordance with regulations prescribed under this chapter, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

(f) Exemptions

The Secretary shall by regulations (issued without regard to subsection (d) of this section) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or device, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

(June 25, 1938, ch. 675, § 706, 52 Stat. 1058; July 12, 1960, Pub. L. 86-618, title I, § 103(b), 74 Stat. 399; Oct. 10, 1962, Pub. L. 87-781, title I, § 104(f)(2), 76 Stat. 785; Oct. 30, 1970, Pub. L. 91-515, title VI, § 601(d)(2), 84 Stat. 1311; May 28, 1976, Pub. L. 94-295, § 9(a), 90 Stat. 583.)

REFERENCES IN TEXT

The General Schedule, referred to in subsec. (b)(5)(D), is set out under section 5332 of Title 5, Government Organization and Employees.

Section 5703(b) of title 5, referred to in subsec. (b)(5)(D), was amended generally by Pub. L. 94-22, § 4, May 19, 1975, 89 Stat. 85, and as so amended does not contain a subsec. (b).

CODIFICATION

"Section 556(d) of title 5" was substituted for "section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c))" on authority of section 7(b) of Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 631, the first section of which enacted Title 5, Government Organization and Employees.

AMENDMENTS

1976—Subsec. (a). Pub. L. 94-295, § 9(a)(2), (3), inserted reference to devices and added provisions directing that color additives for use in or on devices be subject to this section only if the color additives come in direct contact with the body of man or other animals for a significant period of time and authorizing the Secretary to designate by regulation the uses of color additives in or on devices which are subject to this section.

Subsec. (b). Pub. L. 94-295, § 9(a)(1), (2), substituted "drug or device" for "drug" and "drugs or devices" for "drugs" wherever appearing.

Subsec. (f). Pub. L. 94-295, § 9(a)(1), substituted "drug or device" for "drug".

1970—Subsec. (b)(5)(D). Pub. L. 91-515 substituted provisions authorizing members of an advisory committee to receive compensation at rates fixed by the Secretary, with a specific maximum amount, and travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of Title 5, for provisions authorizing such members to receive as compensation a reasonable per diem for time actually spent on committee work, and necessary traveling and subsistence expenses while serving away from their places of residence.

1962—Subsec. (b)(5)(B). Pub. L. 87-781 provided that clause (i) of this subparagraph shall not apply to a color additive in feed of animals raised for food production, if under the conditions of use specified in proposed labeling, and which conditions are reasonably certain to be followed in practice, such additive will not adversely affect the animals and no residue will be found in any edible portion of such animal after slaughter or in any food from the living animal.

1960—Pub. L. 86-618 amended section generally. Section prior to the amendment by Pub. L. 86-618 provided: "The admitting to listing and certification of coal-tar colors, in accordance with regulations prescribed under this chapter, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes."

EFFECTIVE DATE OF 1962 AMENDMENT; EXCEPTIONS

Amendment by Pub. L. 87-781 effective on Oct. 10, 1962, see section 107 of Pub. L. 87-781, set out as an Effective Date of 1962 Amendment note under section 321 of this title.

EFFECTIVE DATE OF 1960 AMENDMENT, TRANSITIONAL PROVISIONS, AND EFFECT ON OTHER LAWS

Title II of Pub. L. 86-618 provided that:

"SEC. 201. [DEFINITIONS.] As used in this title, the term 'basic Act' means the Federal Food, Drug, and Cosmetic Act [this chapter]; the term 'enactment date' means the date of enactment of this Act [July 12, 1960]; and other terms, insofar as also used in the basic Act (whether before or after enactment of this Act) shall have the same meaning as they have, or had when in effect, under the basic Act.

"SEC. 202. [EFFECTIVE DATE.] This Act [amending sections 321, 331, 333, 342, 343, 346, 351, 352, 361, 362, 371, and 376 of this title and repealing sections 354 and 364 of this title] shall, subject to the provisions of section 203, take effect on the enactment date [July 12, 1960].

"SEC. 203. [PROVISIONAL LISTINGS OF COMMERCIALLY ESTABLISHED COLORS.] (a)(1) The purpose of this section is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the basic Act as amended by this Act. A provisional listing (including a deemed provisional listing) of a color additive under this section for any use shall, unless sooner terminated or expiring under the provisions of this section, expire (A) on the closing date (as defined in paragraph (2) of this subsection) or (B) on the effective date of a listing of such additive for such use under section 706 of the basic Act, [this section], whichever date first occurs.

"(2) For the purposes of this section, the term 'closing date' means (A) the last day of the two and one-half year period beginning on the enactment date [July 12, 1960] or (B), with respect to a particular provisional listing (or deemed provisional listing) of a color additive or use thereof, such later closing date as the Secretary may from time to time establish pursuant to the authority of this paragraph. The Secretary may by regulation, upon application of an interested person or on his own initiative, from time to time postpone the original closing date with respect to a provisional listing (or deemed provisional listing) under this section of a specified color additive, or of a specified use or uses of such additive, for such period or periods as he finds necessary to carry out the purpose of this section, if in the Secretary's judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to listing such additive, or such specified use or uses thereof, under section 706 of the basic Act [this section]. The Secretary may terminate a postponement of the closing date at any time if he finds that such postponement should not have been granted, or that by reason of a change in circumstances the basis for such postponement no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such postponement.

"(b) Subject to the other provisions of this section—

"(1) any color additive which, on the day preceding the enactment date [July 12, 1960], was listed and certifiable for any use or uses under section 406(b), 504, or 604 [section 346(b), 354, or 364 of this title], or under the third proviso of section 402(c) [section 342(c) of this title], of the basic Act, and of which a batch or batches had been certified for such use or uses prior to the enactment date [July 12, 1960], and

"(2) any color additive which was commercially used or sold prior to the enactment date [July 12, 1960] for any use or uses in or on any food, drug, or cosmetic, and which either, (A), on the day preceding the enactment date [July 12, 1960], was not a material within the purview of any of the provisions of the basic Act enumerated in paragraph (1) of this subsection, or (B) is the color additive known as synthetic beta-carotene,

shall, beginning on the enactment date [July 12, 1960], be deemed to be provisionally listed under this section as a color additive for such use or uses.

"(c) Upon request of any person, the Secretary, by regulations issued under subsection (d), shall without delay, if on the basis of the data before him he deems such action consistent with the protection of the public health, provisionally list a material as a color additive for any use for which it was listed, and for which a batch or batches of such material had been certified, under section 406(b), 504, or 604 of the basic Act [section 346(b), 354, or 364 of this title] prior to

the enactment date [July 12, 1960], although such color was no longer listed and certifiable for such use under such sections on the day preceding the enactment date. Such provisional listing shall take effect on the date of publication.

"(d)(1) The Secretary shall, by regulations issued or amended from time to time under this section—

"(A) insofar as practicable promulgate and keep current a list or lists of the color additives, and of the particular uses thereof, which he finds are deemed provisionally listed under subsection (b), and the presence of a color additive on such a list with respect to a particular use shall, in any proceeding under the basic Act, be conclusive evidence that such provisional listing is in effect;

"(B) provide for the provisional listing of the color additives and particular uses thereof specified in subsection (c);

"(C) provide, with respect to particular uses for which color additives are or are deemed to be provisionally listed, such temporary tolerance limitations (including such limitations at zero level) and other conditions of use and labeling or packaging requirements, if any, as in his judgment are necessary to protect the public health pending listing under section 706 of the basic Act [this section];

"(D) provide for the certification of batches of such color additives (with or without diluents) for the uses for which they are so listed or deemed to be listed under this section, except that such an additive which is a color additive deemed provisionally listed under subsection (b)(2) of this section shall be deemed exempt from the requirement of such certification while not subject to a tolerance limitation; and

"(E) provide for the termination of a provisional listing (or deemed provisional listing) of a color additive or particular use thereof forthwith whenever in his judgment such action is necessary to protect the public health.

"(2)(A) Except as provided in subparagraph (C) of this paragraph, regulations under this section shall, from time to time, be issued, amended, or repealed by the Secretary without regard to the requirements of the basic Act [subsec. (e) of this section], but for the purposes of the application of section 706(e) of the basic Act (relating to fees) and of determining the availability of appropriations of fees (and of advance deposits to cover fees), proceedings, regulations, and certifications under this section shall be deemed to be proceedings, regulations, and certifications under such section 706 [this section]. Regulations providing for fees (and advance deposits to cover fees), which on the day preceding the enactment date [July 12, 1960] were in effect pursuant to section 706 of the basic Act [this section], shall be deemed to be regulations under such section 706 [this section] as amended by this Act, and appropriations of fees (and advance deposits) available for the purposes specified in such section 706 as in effect prior to the enactment date [July 12, 1960] shall be available for the purposes specified in such section 706 [this section] as so amended.

"(B) If the Secretary, by regulation—

"(i) has terminated a provisional listing (or deemed provisional listing) of a color additive or particular use thereof pursuant to paragraph (1)(E) of this subsection; or

"(ii) has, pursuant to paragraph (1)(C) or paragraph (3) of this subsection, initially established or rendered more restrictive a tolerance limitation or other restriction or requirement with respect to a provisional listing (or deemed provisional listing) which listing had become effective prior to such action,

any person adversely affected by such action may, prior to the expiration of the period specified in clause (A) of subsection (a)(2) of this section, file with the Secretary a petition for amendment of such regulation so as to revoke or modify such action of the Secretary, but the filing of such petition shall not operate to stay or suspend the effectiveness of such action. Such petition shall, in accordance with regulations, set forth the proposed amendment and shall contain data (or refer to data which are before the Secretary or of which he will take official notice), which show that the revocation or modification proposed is consistent with the protection of the public health. The Secretary shall, after publishing such proposal and affording all interested persons an opportunity to present their views thereon orally or in writing, act upon such proposal by published order.

"(C) Any person adversely affected by an order entered under subparagraph (B) of this paragraph may, within thirty days after its publication, file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds for such objections, and requesting a public hearing upon such objections. The Secretary shall hold a public hearing on such objections and shall, on the basis of the evidence adduced at such hearing, act on such objections by published order. Such order may reinstate a terminated provisional listing, or increase or dispense with a previously established temporary tolerance limitation, or make less restrictive any other limitation established by him under paragraph (1) or (3) of this subsection, only if in his judgment the evidence so adduced shows that such action will be consistent with the protection of the public health. An order entered under this subparagraph shall be subject to judicial review in accordance with section 701(f) of the basic Act [section 371(f) of this title] except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. No stay or suspension of such order shall be ordered by the court pending conclusion of such judicial review.

"(D) On and after the enactment date [July 12, 1960], regulations, provisional listings, and certifications (or exemptions from certification) in effect under this section shall, for the purpose of determining whether an article is adulterated or misbranded within the meaning of the basic Act by reason of its being, bearing, or containing a color additive, have the same effect as would regulations, listings, and certifications (or exemptions from certification) under section 706 of the basic Act [this section]. A regulation, provisional listing or termination thereof, tolerance limitation, or certification or exemption therefrom, under this section shall not be the basis for any presumption or inference in any proceeding under section 706 (b) or (c) of the basic Act [subsec. (b) or (c) of this section].

"(3) For the purpose of enabling the Secretary to carry out his functions under paragraphs (1)(A) and (C) of this subsection with respect to color additives deemed provisionally listed, he shall, as soon as practicable after enactment of this Act [July 12, 1960], afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the data so submitted or otherwise before him do not, in his judgment, establish a reliable basis for including such a color additive or particular use or uses thereof in a list or lists promulgated under paragraph (1)(A), or for determining the prevailing level or levels of use thereof prior to the enactment date [July 12, 1960] with a view to prescribing a temporary tolerance or tolerances for such use or uses under paragraph (1)(C), the Secretary shall establish a temporary tolerance limitation at zero level for such use or uses until such time as he finds that it would not be inconsistent with the protection of the public health to increase or dispense with such temporary tolerance limitation.

"SEC. 204. [EFFECT ON MEAT INSPECTION AND POULTRY PRODUCTS INSPECTION ACTS.] Nothing in this Act [amending sections 321, 331, 333, 342, 343, 346, 351,

352, 361, 362, 371, and 376 of this title and repealing sections 354 and 364 of this title] shall be construed to exempt any meat or meat food product, poultry or poultry product, or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended or extended (21 U.S.C. 71 and the following) [now section 601 et seq. of this title] or the Poultry Products Inspection Act (21 U.S.C. 451 and the following)."

EFFECTIVE DATE; ACCELERATION

This section was made "immediately effective" by act May 2, 1939, ch. 107, title I, § 1, 53 Stat. 631.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of two year period following Jan. 5, 1973, and advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of two year period beginning on the date of their establishment, unless in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such two year period, or in the case of a committee established by Congress, its duration is otherwise provided by law, see section 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 331, 342, 343, 346a, 351, 352, 360j, 361, 362, 453, 601, 1033 of this title.

§ 377. Revision of United States Pharmacopoeia; development of analysis and mechanical and physical tests

The Secretary, in carrying into effect the provisions of this chapter, is authorized on and after July 12, 1943, to cooperate with associations and scientific societies in the revision of the United States Pharmacopoeia and in the development of methods of analysis and mechanical and physical tests necessary to carry out the work of the Food and Drug Administration.

(July 12, 1943, ch. 221, title II, § 201, 57 Stat. 500; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

CODIFICATION

Section is from the Labor-Federal Security Appropriation Act, 1944, and not from the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

§ 378. Advertising of foods

(a) Determination of misbranding; notification of Federal Trade Commission by Secretary; contents

(1) Except as provided in subsection (c) of this section, before the Secretary may initiate any action under subchapter III of this chapter—

(A) with respect to any food which the Secretary determines is misbranded under section 343(a)(2) of this title because of its advertising, or

(B) with respect to a food's advertising which the Secretary determines causes the food to be so misbranded,

the Secretary shall, in accordance with paragraph (2), notify in writing the Federal Trade Commission of the action the Secretary proposes to take respecting such food or advertising.

(2) The notice required by paragraph (1) shall—

(A) contain (i) a description of the action the Secretary proposes to take and of the advertising which the Secretary has determined causes a food to be misbranded, (ii) a statement of the reasons for the Secretary's determination that such advertising has caused such food to be misbranded, and

(B) be accompanied by the records, documents, and other written materials which the Secretary determines supports his determination that such food is misbranded because of such advertising.

(b) Action by Federal Trade Commission precluding action by Secretary; exception

(1) If the Secretary notifies the Federal Trade Commission under subsection (a) of this section of action proposed to be taken under subchapter III of this chapter with respect to a food or food advertising and the Commission notifies the Secretary in writing, within the 30-day period beginning on the date of the receipt of such notice, that—

(A) it has initiated under the Federal Trade Commission Act [15 U.S.C. 41 et seq.] an investigation of such advertising to determine if it is prohibited by such Act or any order or rule under such Act,

(B) it has commenced (or intends to commence) a civil action under section 5, 13, or 19 [15 U.S.C. 45, 53, or 57b] with respect to such advertising or the Attorney General has commenced (or intends to commence) a civil action under section 5 [15 U.S.C. 45] with respect to such advertising,

(C) it has issued and served (or intends to issue and serve) a complaint under section 5(b) of such Act [15 U.S.C. 45(b)] respecting such advertising, or

(D) pursuant to section 16(b) of such Act [15 U.S.C. 56(b)] it has made a certification to the Attorney General respecting such advertising,

the Secretary may not, except as provided by paragraph (2), initiate the action described in the Secretary's notice to the Federal Trade Commission.

(2) If, before the expiration of the 60-day period beginning on the date the Secretary receives a notice described in paragraph (1) from the Federal Trade Commission in response to a notice of the Secretary under subsection (a) of this section—

(A) the Commission or the Attorney General does not commence a civil action described in subparagraph (B) of paragraph (1) of this subsection respecting the advertising described in the Secretary's notice,

(B) the Commission does not issue and serve a complaint described in subparagraph (C) of such paragraph respecting such advertising, or

(C) the Commission does not (as described in subparagraph (D) of such paragraph) make a certification to the Attorney General respecting such advertising, or, if the Commission does make such a certification to the Attorney General respecting such advertising, the Attorney General, before the expiration of such period, does not cause appropriate criminal proceedings to be brought against such advertising,

the Secretary may, after the expiration of such period, initiate the action described in the notice to the Commission pursuant to subsection (a) of this section. The Commission shall promptly notify the Secretary of the commencement by the Commission of such a civil action, the issuance and service by it of such a complaint, or the causing by the Attorney General of criminal proceedings to be brought against such advertising.

(c) Secretary's determination of imminent hazard to health as suspending applicability of provisions

The requirements of subsections (a) and (b) of this section do not apply with respect to action under subchapter III of this chapter with respect to any food or food advertising if the Secretary determines that such action is required to eliminate an imminent hazard to health.

(d) Coordination of action by Secretary with Federal Trade Commission

For the purpose of avoiding unnecessary duplication, the Secretary shall coordinate any action taken under subchapter III of this chapter because of advertising which the Secretary determines causes a food to be misbranded with any action of the Federal Trade Commission under the Federal Trade Commission Act [15 U.S.C. 41 et seq.] with respect to such advertising.

(June 25, 1938, ch. 675, § 707, as added Apr. 22, 1976, Pub. L. 94-278, title V, § 502(b), 90 Stat. 412.)

REFERENCES IN TEXT

The Federal Trade Commission Act, referred to in subsecs. (b) and (d), is act Sept. 26, 1914, ch. 311, 38 Stat. 717, as amended, which is classified generally to subchapter I (§ 41 et seq.) of chapter 2 of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see section 58 of Title 15 and Tables volume.

§ 379. Confidential information

The Secretary may provide any information which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of such section to a person other than an officer or employee of the Department if the Secretary determines such other person requires the information in connection with an activity which is undertaken under contract with the Secretary, which relates to the administration of this chapter, and with respect to which the Secretary (or an officer or employee of the Department) is not prohibited from using such information. The Secretary shall require as a condition to the provision of information under this section that the person receiving it take such security precautions respecting the information as the Secretary may by regulation prescribe.

(June 25, 1938, ch. 675, § 708, as added May 28, 1976, Pub. L. 94-295, § 8, 90 Stat. 582.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 331 of this title.

§ 379a. Presumption of existence of jurisdiction

In any action to enforce the requirements of this chapter respecting a device the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.

(June 25, 1938, ch. 675, § 709, as added May 28, 1976, Pub. L. 94-295, § 8, 90 Stat. 583.)

SUBCHAPTER VIII—IMPORTS AND EXPORTS

§ 381. Imports and exports

(a) Imports; list of registered foreign establishments; samples from unregistered foreign establishments; examination and refusal of admission

The Secretary of the Treasury shall deliver to the Secretary of Health, Education, and Welfare, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health, Education, and Welfare and have the right to introduce testimony. The Secretary of Health, Education, and Welfare shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to section 360(i) of this title and shall request that if any drugs and devices manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs and devices be delivered to the Secretary of Health, Education, and Welfare, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health, Education, and Welfare and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 360j(f) of this title, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 355 of this title, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. Clause (2) of the third sentence of this subsection shall not be construed to prohibit the admission of narcotic drugs the importation of which is permit-

ted under the Controlled Substances Import and Export Act [21 U.S.C. 951 et seq.].

(b) Disposition of refused articles

Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health, Education, and Welfare that an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with this chapter or rendered other than a food, drug, device, or cosmetic, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary of Health, Education, and Welfare may, in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Department of Health, Education, and Welfare designated by the Secretary of Health, Education, and Welfare, or an officer or employee of the Department of the Treasury designated by the Secretary of the Treasury.

(c) Charges concerning refused articles

All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any article refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any future importations made by such owner or consignee.

(d) Exports

(1) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this chapter if it—

(A) accords to the specifications of the foreign purchaser,

(B) is not in conflict with the laws of the country to which it is intended for export,

(C) is labeled on the outside of the shipping package that it is intended for export, and

(D) is not sold or offered for sale in domestic commerce.

This paragraph does not authorize the exportation of any new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 360b of this title.

(2) Paragraph (1) does not apply to any device—

(A) which does not comply with an applicable requirement of section 360d or 360e of this title,

(B) which under section 360j(g) of this title is exempt from either such section, or

(C) which is a banned device under section 360f of this title,

unless, in addition to the requirements of paragraph (1), the Secretary has determined that the exportation of the device is not contrary to public health and safety and has the approval of the country to which it is intended for export.

(June 25, 1938, ch. 675, § 801, 52 Stat. 1058; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; Oct. 18, 1949, ch. 696, §§ 1-3, 63 Stat. 882; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Oct. 10, 1962, Pub. L. 87-781, title III, § 306, 76 Stat. 796; July 13, 1968, Pub. L. 90-399, § 106, 82 Stat. 353; Oct. 27, 1970, Pub. L. 91-513, title II, § 701(h), 84 Stat. 1282; May 28, 1976, Pub. L. 94-295, §§ 3(f), 4(b)(3), 90 Stat. 578, 580.)

REFERENCES IN TEXT

The Controlled Substances Import and Export Act, referred to in subsec. (a), is title III of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1285, as amended, which is classified principally to subchapter II (§ 951 et seq.) of chapter 13 of this title. For complete classification of this Act to the Code, see Short Title note under section 951 of this title and Tables volume.

AMENDMENTS

1976—Subsec. (a). Pub. L. 95-295, §§ 3(f)(2), 4(b)(3), expanded provisions requiring the Secretary of Health, Education, and Welfare to request that the Secretary of the Treasury deliver to the Secretary of Health, Education, and Welfare items imported or offered for import into the United States that were manufactured, prepared, propogated, compounded, or processed in non-registered establishments by extending the provisions to include devices imported or offered for import, and, in cl. (1), added reference to devices which were manufactured, packed, stored, or installed using methods, facilities, or controls not conforming to the requirements of section 360j(f) of this title.

Subsec. (d). Pub. L. 94-295, § 3(f)(1), designated existing provisions as par. (1) and added par. (2).

1970—Subsec. (a). Pub. L. 91-513 substituted "Clause (2) of the third sentence of this subsection" for "This subsection" and "the Controlled Substances Import and Export Act" for "section 173 of this title" in the provisions prohibiting a construction of subsec. (a) which might rule out the admission of narcotic drugs expressly permitted under the named statute.

1968—Subsec. (d). Pub. L. 90-399 provided that nothing in subsec. (d) shall authorize the exportation of any new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 360b of this title.

1962—Subsec. (a). Pub. L. 87-781 inserted provisions requiring the Secretary of Health, Education, and Welfare to furnish the Secretary of the Treasury a list of establishments registered under section 360(i) of this title, and to request that samples of any drugs from any establishments not so registered be delivered to the Secretary of Health, Education, and Welfare, with notice of delivery to the consignee who may appear before the Secretary to testify.

1949—Subsec. (a). Act Oct. 18, 1949, § 1, inserted at end of second sentence ", except as provided in subsec-

tion (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury within ninety days of the notice of such refusal or within such additional time as may be permitted pursuant to such regulations.".

Subsec. (b). Act Oct. 18, 1949, § 2, provided for express statutory authority for the long-standing administrative practice of releasing imported articles that do not comply with the requirements of the law so that they may be relabeled or given appropriate treatment to bring them into compliance.

Subsec. (c). Act Oct. 18, 1949, § 3, charged all costs, including salaries and travel and subsistence expenses of officers and employees, against importers.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91-513 effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91-513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment of subsec. (d) of this section by Pub. L. 90-399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90-399, set out as an Effective Date note under section 360b of this title.

SAVINGS PROVISIONS

Amendment by Pub. L. 91-513 not to affect or abate any prosecutions for violation of law or any civil seizure or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotic and Dangerous Drugs [now Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91-513, set out as a Savings Provisions note under section 321 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare, and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 334, 360, 371 of this title.

SUBCHAPTER IX—MISCELLANEOUS

§ 391. Separability clause

If any provision of this chapter is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the chapter and the applicability thereof to other persons and circumstances shall not be affected thereby.

(June 25, 1938, ch. 675, § 901, 52 Stat. 1059.)

§ 392. Exemption of meats and meat food products; laws unaffected

(a) Meats and meat food products shall be exempt from the provisions of this chapter to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended [21 U.S.C. 601 et seq.].

(b) Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of section 351 of Public Health Service Act [42 U.S.C. 262] (relating to viruses, serums, toxins, and analogous products applicable to man); the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913 [21 U.S.C. 151 et seq.]; the Filled Cheese Act of June 6, 1896 (U.S.C., 1934 ed., title 26, ch. 10), the Filled Milk Act of March 4, 1923 [21 U.S.C. 61 et seq.]; or the Import Milk Act of February 15, 1927 [21 U.S.C. 141 et seq.].

(June 25, 1938, ch. 675, § 902(b), (c), 52 Stat. 1059; July 13, 1968, Pub. L. 90-399, § 107, 82 Stat. 353.)

REFERENCES IN TEXT

The Meat Inspection Act, approved March 4, 1907, as amended, referred to in subsec. (a), is act Mar. 4, 1907, ch. 2907, titles I to IV, as added Dec. 15, 1967, Pub. L. 90-201, 81 Stat. 584, which are classified generally to subchapters I to IV (§ 601 et seq.) of chapter 12 of this title. For complete classification of this Act to the Code, see Short Title note under section 601 of this title and Tables volume.

The Act of March 4, 1913, referred to in subsec. (b), is act Mar. 4, 1913, ch. 145, 37 Stat. 828. The provisions of such act relating to viruses, etc., applicable to domestic animals, popularly known as the Virus-Serum-Toxin Act, are classified generally to chapter 5 (§ 151 et seq.) of this title. For complete classification of this Act to the Code, see Tables volume.

The Filled Cheese Act of June 6, 1896 (U.S.C., 1934 ed., title 26, ch. 10), referred to in subsec. (b), is act June 6, 1896, ch. 337, 29 Stat. 253, which had been classified to chapter 10 (§ 1000 et seq.) of Title 26, Internal Revenue, and included as chapter 17 (§ 2350 et seq.) of Title 26, Internal Revenue Code of 1939. Such chapter 17 was covered by section 4831 et seq. of Title 26, Internal Revenue Code, prior to the repeal of section 4831 et. seq. of Title 26 by Pub. L. 93-490, § 3(a)(1), Oct. 26, 1974, 88 Stat. 1466.

The Filled Milk Act of March 4, 1923, referred to in subsec. (b), is act Mar. 4, 1923, ch. 262, 42 Stat. 1486, which is classified generally to chapter 3 (§ 61 et seq.) of this title. For complete classification of this Act to the Code, see Tables volume.

The Import Milk Act of February 15, 1927, referred to in subsec. (b), is act Feb. 15, 1927, ch. 155, 44 Stat. 1101, which is classified generally to subchapter IV (§ 141 et seq.) of chapter 4 of this title. For complete classification of this Act to the Code, see Tables volume.

CODIFICATION

Subsecs. (a) and (b) of this section comprise respectively subsecs. (b) and (c) of act June 25, 1938. Subsecs. (a) and (d) of act June 25, 1938, which prescribed the effective date of this chapter and made appropriations available, are set out as notes under section 301 of this title and this section, respectively.

AMENDMENTS

1968—Subsec. (b). Pub. L. 90-399 substituted "section 262 of title 42 (relating to viruses, serums, toxins, and analogous products applicable to man)" for "the virus serum, and toxin Act of July 1, 1902" and inserted reference to "the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913".

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment of subsec. (b) of this section by Pub. L. 90-399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L.

90-399, set out as an Effective Date note under section 360b of this title.

AVAILABILITY OF APPROPRIATIONS

Section 902(d) of act June 25, 1938, provided that: "In order to carry out the provisions of this Act [affecting sections 1 to 15, 301 et seq. of this title] which take effect prior to the repeal of the Food and Drugs Act of June 30, 1906, as amended [sections 1 to 15 of this title], appropriations available for the enforcement of such Act of June 30, 1906, are also authorized to be made available to carry out such provisions."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 679 of this title.

CHAPTER 10—POULTRY AND POULTRY PRODUCTS INSPECTION

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This chapter is referred to in section 321 of this title.

§ 451. Congressional statement of findings

Poultry and poultry products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded poultry products impair the effective regulation of poultry products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged poultry products, and result in sundry losses to poultry producers and processors of poultry and poultry products, as well as injury to consumers. It is hereby found that all articles and poultry which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary of Agriculture and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

(Pub. L. 85-172, § 2, Aug. 28, 1957, 71 Stat. 441; Pub. L. 90-492, § 2, Aug. 18, 1968, 82 Stat. 791.)

AMENDMENTS

1968—Pub. L. 90-492 added provisions stating it to be necessary that the health and welfare of consumers be protected by assuring that poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged, provisions that misbranded poultry products impair the effective regulation of poultry products and destroy markets for wholesome, not adulterated, and properly labeled and packaged poultry products, and result in sundry losses to poultry producers and processors of poultry and poultry products, as well as injury to consumers, and provisions that all articles and poultry which are regulated by this chapter are either in interstate or foreign commerce or substantially affect such commerce and that regulation by the Secretary of Agriculture and cooperation by the states and other jurisdictions as contemplated by this chapter are appropriate to serve the specified aims, and struck out provisions that all poultry and poultry products which have or are required to have inspection under this chapter are either in the current of interstate or foreign commerce or directly affect such commerce, provisions that that part entering directly into the current of interstate or foreign commerce cannot be effectively inspected and regulated without also inspecting and regulating all poultry and poultry products in the same establishment, and provisions authorizing the Secretary to designate major consuming areas.

EFFECTIVE DATE OF 1968 AMENDMENT

Section 20 of Pub. L. 90-492 provided that:

"This Act [see Short Title note below] shall become effective upon enactment [Aug. 18, 1968] except as provided in paragraphs (a) through (c):

"(a) The provisions of subparagraphs (a)(2)(A) and (a)(3) of section 9 of the Poultry Products Inspection Act, as amended by section 9 of this Act [section 458(a)(2)(A) and (a)(3) of this title], shall become effective upon the expiration of sixty days after enactment hereof [Aug. 18, 1968].

"(b) Section 14 of this Act, amending section 15 of the Poultry Products Inspection Act [section 464 of this title], shall become effective upon the expiration of sixty days after enactment hereof [Aug. 18, 1968].

"(c) Paragraph 11(d) of the Poultry Products Inspection Act, as added by section 11 of this Act [section 460(d) of this title], shall become effective upon the expiration of sixty days after enactment hereof [Aug. 18, 1968]."

EFFECTIVE DATE

Section 29, formerly section 22 of Pub. L. 85-172, as renumbered by Pub. L. 90-492, § 17, Aug. 18, 1968, 82 Stat. 805, provided that: "This Act [this chapter] shall take effect upon enactment [August 28, 1957], except that no person shall be subject to the provisions of this Act [this chapter] prior to January 1, 1959, unless such person after January 1, 1958, applies for and receives inspection for poultry or poultry products in accordance with the provisions of this Act [this chapter] and pursuant to regulations promulgated by the Secretary hereunder, in any establishment processing poultry or poultry products in commerce or in a designated major consuming area. Any person who voluntarily applies for and receives such inspection after January 1, 1958, shall be subject, on and after the date he commences to receive such inspection, to all of the provisions and penalties provided for in this Act [this chapter] with respect to all poultry or poultry products handled in the establishment for which such said application for inspection is made."

SHORT TITLE OF 1968 AMENDMENT

Section 1 of Pub. L. 90-492 provided: "That this Act [which added sections 467a to 467f and 470 of this title, amended sections 451 to 461, 463 to 465, and 467 of this title, and enacted provisions set out as notes under this section] may be cited as the 'Wholesome Poultry Products Act'."

SHORT TITLE

Congress in enacting Pub. L. 85-172, which comprises this chapter, provided by section 1 of the act that it should be popularly known as the "Poultry Products Inspection Act".

SEPARABILITY OF PROVISIONS OF PUB. L. 90-492

Section 19 of Pub. L. 90-492 provided that: "If any provisions of this Act or of the amendments made hereby [see Short Title note above] or the application thereof to any person or circumstances is held invalid, the validity of the remainder of the Act and the remaining amendments and of the application of such

provision to other persons and circumstances shall not be effected thereby."

SEPARABILITY OF PROVISIONS

Section 28, formerly section 21 of Pub. L. 85-172 as renumbered by Pub. L. 90-492, § 17, Aug. 18, 1968, 82 Stat. 805, provided that: "If any provision of this Act [this chapter] or the application thereof to any person or circumstances is held invalid, the validity of the remainder of the Act [this chapter] and of the application of such provision to other persons and circumstances shall not be affected thereby."

FOOD ADDITIVES AMENDMENT OF 1958

Pub. L. 85-929, § 7, Sept. 6, 1958, 72 Stat. 1789, provided that: "Nothing in this Act [amending sections 321, 331, 342, 346, 348 of this title and section 210 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under sections 321, 342, and 451 of this title] shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Poultry Products Inspection Act (21 U.S.C. 451 and the following) [this chapter] or the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended and extended (21 U.S.C. 71 and the following) [now covered by section 601 et seq. of this title]."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 454 of this title.

ACT REFERRED TO IN OTHER SECTIONS

The Wholesome Poultry Products Act is referred to in section 1053 of this title.

§ 452. Congressional declaration of policy

It is hereby declared to be the policy of the Congress to provide for the inspection of poultry and poultry products and otherwise regulate the processing and distribution of such articles as hereinafter prescribed to prevent the movement or sale in interstate or foreign commerce of, or the burdening of such commerce by, poultry products which are adulterated or misbranded. It is the intent of Congress that when poultry and poultry products are condemned because of disease, the reason for condemnation in such instances shall be supported by scientific fact, information, or criteria, and such condemnation under this chapter shall be achieved through uniform inspection standards and uniform applications thereof.

(Pub. L. 85-172, § 3, Aug. 28, 1957, 71 Stat. 441; Pub. L. 90-492, § 3, Aug. 18, 1968, 82 Stat. 792.)

AMENDMENTS

1968—Pub. L. 90-492 added provisions declaring the policy of Congress to be to otherwise regulate the processing and distribution of poultry and poultry products as hereinafter prescribed so as to prevent the movement or sale in interstate commerce of, or the burdening of such commerce by poultry products which are adulterated or misbranded, and provisions that declared the policy of Congress to be that condemnation of diseased poultry and poultry products shall be achieved through uniform inspection standards and supported by scientific fact or criteria, and struck out provisions that declared the policy of Congress to be to provide for inspection by the inspection service to prevent the movement in interstate commerce or foreign commerce or in a designated major consuming area of poultry products which are unwholesome, adulterated, or otherwise unfit for human food.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90-492 effective Aug. 18, 1968, see section 20 of Pub. L. 90-492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 454 of this title.

§ 453. Definitions

For purposes of this chapter—

(a) The term "commerce" means commerce between any State, any territory, or the District of Columbia, and any place outside thereof; or within any territory not organized with a legislative body, or the District of Columbia.

(b) Except as otherwise provided in this chapter, the term "State" means any State of the United States and the Commonwealth of Puerto Rico.

(c) The term "territory" means Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States, excluding the Canal Zone.

(d) The term "United States" means the States, the District of Columbia, and the territories of the United States.

(e) The term "poultry" means any domesticated bird, whether live or dead.

(f) The term "poultry product" means any poultry carcass, or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof, excepting products which contain poultry ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the poultry food industry, and which are exempted by the Secretary from definition as a poultry product under such conditions as the Secretary may prescribe to assure that the poultry ingredients in such products are not adulterated and that such products are not represented as poultry products.

(g) The term "adulterated" shall apply to any poultry product under one or more of the following circumstances:

(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)(A) if it bears or contains (by reason of administration of any substance to the live poultry or otherwise) any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;

(B) if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title;

(C) if it bears or contains any food additive which is unsafe within the meaning of section 348 of this title;

(D) if it bears or contains any color additive which is unsafe within the meaning of section 376 of this title: *Provided*, That an article which is not otherwise deemed adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in official establishments;

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) if it is, in whole or in part, the product of any poultry which has died otherwise than by slaughter;

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title;

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(h) The term "misbranded" shall apply to any poultry product under one or more of the following circumstances:

(1) if its labeling is false or misleading in any particular;

(2) if it is offered for sale under the name of another food;

(3) if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter, the name of the food imitated;

(4) if its container is so made, formed, or filled as to be misleading;

(5) unless it bears a label showing (A) the name and the place of business of the manufacturer, packer, or distributor; and (B) an accurate statement of the quantity of the product in terms of weight, measure, or numerical count: *Provided*, That under clause (B) of this subparagraph (5), reasonable variations may be permitted, and exemptions as to small packages or articles not in packages or other containers may be established by regulations prescribed by the Secretary;

(6) if any word, statement, or other information required by or under authority of this chapter to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) if it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations of the Secretary under section 457 of this title unless (A) it conforms to such definition and standard, and (B) its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) if it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by regulations of the Secretary under section 457 of this title, and it falls below the standard to fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(9) if it is not subject to the provisions of subparagraph (7), unless its label bears (A) the common or usual name of the food, if any there be, and (B) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings may, when authorized by the Secretary, be designated as spices, flavorings, and colorings without naming each: *Provided*, That to the extent that compliance with the requirements of clause (B) of this subparagraph (9) is impracticable or results in deception or unfair competion, exemptions shall be established by regulations promulgated by the Secretary;

(10) if it purports to be or is represented for special dietary uses unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary, after consultation with the Secretary of Health, Education, and Welfare, determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses;

(11) if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative unless it bears labeling stating that fact: *Provided*, That, to the extent that compliance with the requirements of this subparagraph (11) is impracticable, exemptions shall be established by regulations promulgated by the Secretary; or

(12) if it fails to bear on its containers, and in the case of nonconsumer packaged carcasses (if the Secretary so requires) directly thereon, as the Secretary may by regulations prescribe, the official inspection legend and official establishment number of the establishment where the article was processed, and, unrestricted by any of the foregoing, such other information as the Secretary may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

(i) The term "Secretary" means the Secretary of Agriculture or his delegate.

(j) The term "person" means any individual, partnership, corporation, association, or other business unit.

(k) The term "inspector" means: (1) an employee or official of the United States Government authorized by the Secretary to inspect poultry and poultry products under the authority of this chapter, or (2) any employee or official of the government of any State or territory or the District of Columbia authorized by the Secretary to inspect poultry and poultry products under authority of this chapter, under an agreement entered into between the Secretary and the appropriate State or other agency.

(l) The term "official mark" means the official inspection legend or any other symbol prescribed by regulation of the Secretary to identify the status of any article or poultry under this chapter.

(m) The term "official inspection legend" means any symbol prescribed by regulations of the Secretary showing that an article was inspected for wholesomeness in accordance with this chapter.

(n) The term "official certificate" means any certificate prescribed by regulations of the Secretary for issuance by an inspector or other person performing official functions under this chapter.

(o) The term "official device" means any device prescribed or authorized by the Secretary for use in applying any official mark.

(p) The term "official establishment" means any establishment as determined by the Secretary at which inspection of the slaughter of poultry, or the processing of poultry products, is maintained under the authority of this chapter.

(q) The term "inspection service" means the official Government service within the Department of Agriculture designated by the Secretary as having the responsibility for carrying out the provisions of this chapter.

(r) The term "container" or "package" includes any box, can, tin, cloth, plastic, or other receptacle, wrapper, or cover.

(s) The term "label" means a display of written, printed, or graphic matter upon any article or the immediate container (not including packaged liners) of any article; and the term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(t) The term "shipping container" means any container used or intended for use in packaging the product packed in an immediate container.

(u) The term "immediate container" includes any consumer package; or any other container in which poultry products, not consumer packaged, are packed.

(v) The term "capable of use as human food" shall apply to any carcass, or part or product of a carcass, of any poultry, unless it is denatured or otherwise identified as required by regulations prescribed by the Secretary to deter its use as human foods, or it is naturally inedible by humans.

(w) The term "processed" means slaughtered, canned, salted, stuffed, rendered, boned, cut up, or otherwise manufactured or processed.

(x) The term "Federal Food, Drug, and Cosmetic Act" means the Act so entitled, approved June 25, 1938 (52 Stat. 1040) [21 U.S.C. 301 et seq.], and Acts amendatory thereof or supplementary thereto.

(y) The terms "pesticide chemical," "food additive", "color additive", and "raw agricultural commodity" shall have the same meanings for purposes of this chapter as under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(z) The term "poultry products broker" means any person engaged in the business of buying or selling poultry products on commission, or otherwise negotiating purchases or sales of such articles other than for his own account or as an employee of another person.

(aa) The term "renderer" means any person engaged in the business of rendering carcasses, or parts or products of the carcasses, of poultry, except rendering conducted under inspection or exemption under this chapter.

(bb) The term "animal food manufacturer" means any person engaged in the business or manufacturing or processing animal food derived wholly or in part from carcasses, or parts or products of the carcasses, of poultry.

(Pub. L. 85-172, § 4, Aug. 28, 1957, 71 Stat. 441; Pub. L. 87-498, June 25, 1962, 76 Stat. 110; Pub. L. 90-492, § 4, Aug. 18, 1968, 82 Stat. 792.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in pars. (x) and (y), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables volume.

AMENDMENTS

1968—Pub. L. 90-492 added the definitions of "State", "territory", "United States", "misbranded", "official mark", "official inspection legend", "official certificate", "official device", "capable of use as human food", "processed", "Federal Food, Drug, and Cosmetic Act", "pesticide chemical", "poultry products broker", "renderer", and "animal food manufacturer", revised the definitions of "commerce", "poultry", "poultry product", "adulterated", "Secretary", "inspector", "container" or "package," "label," and "immediate container", reenacted without change the definitions of "person", "official establishment", "inspection service", and "shipping container", and deleted the definition of "wholesome", "unwholesome", and "official inspection mark".

1962—Par. (a). Pub. L. 87-498 deleted references to Territories or possessions, and added the definition of "State".

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90-492 effective Aug. 18, 1968, see section 20 of Pub. L. 90-492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 457, 461, 464 of this title; title 15 sections 2052, 2602.

§ 454. Federal and state cooperation in development and administration of state poultry product inspection programs

(a) State laws; planning, technical and financial assistance; advisory committees

It is the policy of the Congress to protect the consuming public from poultry products that are adulterated or misbranded and to assist in efforts by State and other government agencies to accomplish this objective. In furtherance of this policy—

(1) The Secretary is authorized, whenever he determines that it would effectuate the purposes of this chapter, to cooperate with the appropriate State agency in developing and administering a State poultry product inspection program in any State which has enacted a mandatory State poultry product inspection law that imposes ante mortem and post mortem inspection, reinspection and sanitation requirements that are at least equal to those under this chapter, with respect to all or certain classes of persons engaged in the State in slaughtering poultry or processing poultry products for use as human food solely for distribution within such State.

(2) The Secretary is further authorized, whenever he determines that it would effectuate the purposes of this chapter, to cooperate with appropriate State agencies in developing and administering State programs under State laws containing authorities at least equal to those provided in section 460 of this title; and to cooperate with other agencies of the United States in carrying out any provisions of this chapter. In carrying out the provisions of this chapter, the Secretary may conduct such examinations, investigations, and inspections as he determines practicable through any officer or employee of any State or Territory or the District of Columbia commissioned by the Secretary for such purpose.

(3) Cooperation with State agencies under this section may include furnishing to the appropriate State agency (i) advisory assistance in planning and otherwise developing an adequate State program under the State law; and (ii) technical and laboratory assistance and training (including necessary curricular and instructional materials and equipment), and financial and other aid for administration of such a program. The amount to be contributed to any State by the Secretary under this section from Federal funds for any year shall not exceed 50 per centum of the estimated total cost of the cooperative program; and the Federal funds shall be allocated among the States desiring to cooperate on an equitable basis. Such cooperation and payment shall be contingent at all times upon the administration of the State program in a manner which the Secretary, in consultation with the appropriate advisory committee appointed under subparagraph (4), deems adequate to effectuate the purposes of this section.

(4) The Secretary may appoint advisory committees consisting of such representatives of appropriate State agencies as the Secretary and the State agencies may designate to consult with him concerning State and Federal programs with respect to poultry product inspection and other matters within the scope of this chapter, including evaluating State programs for purposes of this chapter, and obtaining better coordination and more uniformity among the State programs and between the Federal and State programs and adequate protection of consumers.

(b) Appropriate state agency; performance of functions by subordinate governmental unit

The appropriate State agency with which the Secretary may cooperate under this chapter shall be a single agency in the State which is primarily responsible for the coordination of the State programs having objectives similar to those under this chapter. When the State program includes performance of certain functions by a municipality or other subordinate governmental unit, such unit shall be deemed to be a part of the State agency for purposes of this section.

(c) Intrastate activities; designation of state for regulation; publication of designation; exempted operations; termination of designation; review of operations in nondesignated states; annual report

(1) If the Secretary has reason to believe, by thirty days prior to the expiration of two years after August 18, 1968, that a State has failed to develop or is not enforcing, with respect to all establishments within its jurisdiction (except those that would be exempted from Federal inspection under subparagraph (2) of this paragraph (c)) at which poultry are slaughtered, or poultry products are processed for use as human food, solely for distribution within such State, and the products of such establishments, requirements at least equal to those imposed under sections 451 to 453, 455 to 459, 461 to 467d of this title, he shall promptly notify the Governor of the State of this fact. If the Secretary determines, after consultation with the Governor of the State, or representative selected by him, that such requirements have not been developed and activated, he shall promptly after the expiration of such two-year period designate such State as one in which the provisions of said sections of this chapter shall apply to operations and transactions wholly within such State: *Provided,* That if the Secretary has reason to believe that the State will activate such requirements within one additional year, he may delay such designation for said period, and not designate the State, if he determines at the end of the year that the State then has such requirements in effective operation. The Secretary shall publish any such designation in the Federal Register and, upon the expiration of thirty days after such publication, the provisions of said sections of this chapter shall apply to operations and transactions and to persons engaged therein in the State to the same extent and in the same manner as if such operations and transactions were conducted in or for commerce. However, notwithstanding any other provision of this section, if the Secretary determines that any establishment within a State is producing adulterated poultry products for distribution within such State which would clearly endanger the public health he shall notify the Governor of the State and the appropriate advisory committee provided for by subparagraph (a)(4) of this section of such fact for effective action under State or local law. If the State

does not take action to prevent such endangering of the public health within a reasonable time after such notice, as determined by the Secretary, in light of the risk to public health, the Secretary may forthwith designate any such establishment as subject to the provisions of said sections of this chapter, and thereupon the establishment and operator thereof shall be subject to such provisoins as though engaged in commerce until such time as the Secretary determines that such State has developed and will enforce requirements at least equal to those imposed under said sections.

(2) The provisions of this chapter requiring inspection of the slaughter of poultry and the processing of poultry products shall not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments if such establishment are subject to such inspection provisions only under this paragraph (c).

(3) Whenever the Secretary determines that any State designated under this paragraph (c) has developed and will enforce State poultry products inspection requirements at least equal to those imposed under the aforesaid sections of this chapter, with respect to the operations and transactions within such State which are regulated under subparagraph (1) of this paragraph (c), he shall terminate the designation of such State under this paragraph (c), but this shall not preclude the subsequent redesignation of the State at any time upon thirty days' notice to the Governor and publication in the Federal Register in accordance with this paragraph, and any State may be designated upon such notice and publication, at any time after the period specified in this paragraph whether or not the State has theretofore been designated, upon the Secretary determining that it is not effectively enforcing requirements at least equal to those imposed under said sections.

(4) The Secretary shall promptly after August 18, 1968, and periodically thereafter, but at least annually, review the requirements, including the enforcement thereof, of the several States not designated under this paragraph (c), with respect to the slaughter, and the processing, storage, handling, and distribution of poultry products, and inspection of such operations, and annually report thereon to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate in the report required in section 470 of this title.

(d) Definition

As used in this section, the term "State" means any State (including the Commonwealth of Puerto Rico) or organized territory.

(Pub. L. 85–172, § 5, Aug. 28, 1957, 71 Stat. 443; Pub. L. 90–492, § 5, Aug. 18, 1968, 82 Stat. 796; S. Res. 4, Feb. 4, 1977.)

CODIFICATION

The phrase "after August 18, 1968," was substituted for original "upon enactment of the Wholesome Poultry Products Act,".

AMENDMENTS

1968—Pub. L. 90-492 substituted provisions authorizing the Secretary to cooperate with the appropriate state agency in the development and administration of state poultry product inspection programs in those states having mandatory poultry product inspection laws and those states having laws at least equal to the provisions of section 460 of this title, provisions authorizing planning, technical and financial assistance and the appointment of advisory committees, provisions designating the appropriate state agency with which the Secretary may cooperate, provisions authorizing the Secretary to designate states as subject to the regulatory provisions of this chapter when the requirements of the specified section have not been complied with or when the specified intrastate activities are present, provisions exempting from the requirements of this chapter operations of the types traditionally and usually conducted at retail stores and restaurants, provisions authorizing the Secretary to terminate the aforementioned designation of states as subject to the regulatory provisions of this chapter, and provisions authorizing the Secretary to review the operations in nondesignated states and make an annual report thereon, for provisions authorizing the Secretary, upon application by any appropriate state or local official or agency or by any appropriate local poultry industry group and after public hearing, to designate major consuming areas as subject to the regulatory provisions of this chapter where the Secretary finds that poultry or poultry products are handled or consumed in such volume as to affect, burden or obstruct the movement of inspected poultry products in interstate commerce.

CHANGE OF NAME

The Committee on Agriculture and Forestry of the Senate was abolished and replaced by the Committee on Agriculture, Nutrition, and Forestry of the Senate, effective Feb. 11, 1977. See Rule XXV of the Standing Rules of the Senate, as amended by Senate Resolution 4 (popularly cited as the "Committee System Reorganization Amendments of 1977"), approved Feb. 4, 1977.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90-492 effective Aug. 18, 1968, see section 20 of Pub. L. 90-492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 457, 460 of this title.

§ 455. Inspection in official establishments

(a) Ante mortem inspection

For the purpose of preventing the entry into or flow or movement in commerce of, or the burdening of commerce by, any poultry product which is capable of use as human food and is adulterated, the Secretary shall, where and to the extent considered by him necessary, cause to be made by inspectors ante mortem inspection of poultry in each official establishment processing poultry or poultry products for commerce or otherwise subject to inspection under this chapter.

(b) Post mortem inspection; quarantine, segregation, and reinspection

The Secretary, whenever processing operations are being conducted, shall cause to be made by inspectors post mortem inspection of the carcass of each bird processed, and at any time such quarantine, segregation, and reinspection as he deems necessary of poultry and poultry products capable of use as human food

in each official establishment processing such poultry or poultry products for commerce or otherwise subject to inspection under this chapter.

(c) Condemnation; appeal; reprocessing

All poultry carcasses and parts thereof and other poultry products found to be adulterated shall be condemned and shall, if no appeal be taken from such determination of condemnation, be destroyed for human food purposes under the supervision of an inspector: *Provided*, That carcasses, parts, and products, which may by reprocessing be made not adulterated, need not be so condemned and destroyed if so reprocessed under the supervision of an inspector and thereafter found to be not adulterated. If an appeal be taken from such determination, the carcasses, parts, or products shall be appropriately marked and segregated pending completion of an appeal inspection, which appeal shall be at the cost of the appellant if the Secretary determines that the appeal is frivolous. If the determination of condemnation is sustained the carcasses, parts, and products shall be destroyed for human food purposes under the supervision of an inspector.

(Pub. L. 85–172, § 6, Aug. 28, 1957, 71 Stat. 443; Pub. L. 90–492, § 6, Aug. 18, 1968, 82 Stat. 798.)

AMENDMENTS

1968—Par. (a). Pub. L. 90–492, § 6(a), substituted "of, or the burdening of commerce by, any poultry product which is capable of use as human food and is adulterated," for "or a designated major consuming area of any poultry product which is unwholesome or adulterated," "each official establishment" for "any official establishment", and "otherwise subject to inspection under this chapter" for "in, or for marketing in a designated city or area".

Par. (b). Pub. L. 90–492, § 6(b), substituted "segregation, and reinspection" for "segregation, reinspection", and "otherwise subject to inspection under this chapter" for "in, or for marketing in a designated city or area", and added "capable of use as human food" following "necessary of poultry and poultry products".

Par. (c). Pub. L. 90–492, § 6(c), added "other" preceding "poultry products", and substituted "to be adulterated" for "to be unwholesome or adulterated", "made not adulterated" for "made not unwholesome and not adulterated", and "to be not adulterated" for "to be not unwholesome and not adulterated".

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 467 of this title.

§ 456. Operation of premises, facilities and equipment

(a) Sanitary practices

Each official establishment slaughtering poultry or processing poultry products for commerce or otherwise subject to inspection under this chapter shall have such premises, facilities, and equipment, and be operated in accordance with such sanitary practices, as are required by regulations promulgated by the Secretary for the purpose of preventing the entry into or flow or movement in commerce or burdensome effect upon commerce, of poultry products which are adulterated.

(b) Refusal of inspection

The Secretary shall refuse to render inspection to any establishment whose premises, facilities, or equipment, or the operation thereof, fail to meet the requirements of this section.

(Pub. L. 85–172, § 7, Aug. 28, 1957, 71 Stat. 444; Pub. L. 90–492, § 7, Aug. 18, 1968, 82 Stat. 799.)

AMENDMENTS

1968—Par. (a). Pub. L. 90–492 substituted "otherwise subject to inspection under this chapter" for "in or for marketing in a designated major consuming area", "burdensome effect upon commerce" for "in a designated major consuming area", and "which are adulterated" for "which are unwholesome or adulterated".

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 467 of this title.

§ 457. Labeling and container standards

(a) Requirements for shipping containers and immediate containers; nonconsumer packaged carcasses

All poultry products inspected at any official establishment under the authority of this chapter and found to be not adulterated, shall at the time they leave the establishment bear, in distinctly legible form, on their shipping containers and immediate containers as the Secretary may require, the information required under paragraph (h) of section 453 of this title. In addition, the Secretary whenever he determines such action is practicable and necessary for the protection of the public, may require nonconsumer packaged carcasses at the time they leave the establishment to bear directly thereon in distinctly legible form any information required under such paragraph (h).

(b) Labeling requirements; definitions and standards of identity or composition or articles and standards of fill of container; standards consistent with Federal Food, Drug, and Cosmetic Act; consistency between Federal and state standards

The Secretary, whenever he determines such action is necessary for the protection of the public, may prescribe: (1) the styles and sizes of type to be used with respect to material required to be incorporated in labeling to avoid false or misleading labeling in marketing and labeling any articles or poultry subject to this chapter; (2) definitions and standards of identity or composition or articles subject to this chapter and standards of fill of container for such articles not inconsistent with any such standards established under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], and there shall be consultation between the Secretary and the Secretary of Health, Education, and Welfare prior to the issuance of such standards under either Act relating to articles subject to this chapter to avoid inconsistency in such standards and possible impairment of the coordinated effective administration of this

chapter and the Federal Food, Drug, and Cosmetic Act. There shall also be consultation between the Secretary and an appropriate advisory committee provided for in section 454 of this title, prior to the issuance of such standards under this chapter, to avoid, insofar as feasible, inconsistency between Federal and State standards.

(c) Use of trade names; false or misleading marking or labeling; misleading form or size of container

No article subject to this chapter shall be sold or offered for sale by any person in commerce, under any name or other marking or labeling which is false or misleading, or in any container of a misleading form or size, but established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted.

(d) Withholding use of false or misleading mark, label, or container size or form; modification; hearing; conclusiveness of determination; appeal

If the Secretary has reason to believe that any marking or labeling or the size or form of any container in use or proposed for use with respect to any article subject to this chapter is false or misleading in any particular, he may direct that such use be withheld unless the marking, labeling, or container is modified in such manner as he may prescribe so that it will not be false or misleading. If the person using or proposing to use the marketing, labeling, or container does not accept the determination of the Secretary, such person may request a hearing, but the use of the marking, labeling, or container shall, if the Secretary so directs, be withheld pending hearing and final determination by the Secretary. Any such determination by the Secretary shall be conclusive unless, within thirty days after receipt of notice of such final determination, the person adversely affected thereby appeals to the United States Court of Appeals for the circuit in which such person has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit. The provisions of section 194 of title 7 shall be applicable to appeals taken under this section.

(Pub. L. 85-172, § 8, Aug. 28, 1957, 71 Stat. 444; Pub. L. 90-492, § 8, Aug. 18, 1968, 82 Stat. 799.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables volume.

AMENDMENTS

1968—Par. (a). Pub. L. 90-492 substituted provisions requiring shipping containers and immediate containers, as the Secretary may order, to bear the information required under section 453(h) of this title, and provisions, whenever the Secretary determines such action to be practicable and necessary, requiring nonconsumer packaged carcasses at the time they leave the official establishment to bear the information required under the aforementioned section, for provisions requiring shipping containers to bear the official mark and the approved plant number of the official establishment in which the contents were processed, provisions requiring immediate containers to bear the official inspection mark, the name of the product, a statement of ingredients, the net weight or other appropriate measure of the contents, the name and address of the processor, and the approved plant number of the official establishment in which the contents were processed, and provisions authorizing the Secretary to make reasonable variations and grant exemptions from the foregoing labeling requirements.

Par. (b). Pub. L. 90-492 added par. (b). Provisions of former par. (b). were redesignated as pars. (c) and (d).

Par. (c). Pub. L. 90-492 redesignated part of the provisions of former par. (b) as (c), and made changes in phraseology.

Par. (d). Pub. L. 90-492 redesignated part of the provisions of former par. (b) as (d), and, as so redesignated, extended the authority of the Secretary to withhold from use products which have false or misleading markings or containers.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90-492 effective Aug. 18, 1968, see section 20 of Pub. L. 90-492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 453, 454, 467, 467c of this title.

§ 458. Prohibited acts

(a) No person shall—

(1) slaughter any poultry or process any poultry products which are capable of use as human food at any establishment processing any such articles for commerce, except in compliance with the requirements of this chapter;

(2) sell, transport, offer for sale or transportation, or receive for transportation, in commerce, (A) any poultry products which are capable of use as human food and are adulterated or misbranded at the time of such sale, transportation, offer for sale or transportation, or receipt for transportation; or (B) any poultry products required to be inspected under this chapter unless they have been so inspected and passed;

(3) do, with respect to any poultry products which are capable of use as human food, any act while they are being transported in commerce or held for sale after such transportation, which is intended to cause or has the effect of causing such products to be adulterated or misbranded;

(4) sell, transport, offer for sale or transportation, or receive for transportation, in commerce or from an official establishment, any slaughtered poultry from which the blood, feathers, feet, head, or viscera have not been removed in accordance with regulations promulgated by the Secretary, except as may be authorized by regulations of the Secretary;

(5) use to his own advantage, or reveal other than to the authorized representatives of the United States Government or any State or other government in their official capacity, or as ordered by a court in any judicial proceedings, any information acquired under the authority of this chapter concerning any matter which is entitled to protection as a trade secret.

(b) No brand manufacturer, printer, or other person shall cast, print, lithograph, or otherwise make any device containing any official

mark or simulation thereof, or any label bearing any such mark or simulation, or any form of official certificate or simulation thereof, except as authorized by the Secretary.

(c) No person shall—

(1) forge any official device, mark, or certificate;

(2) without authorization from the Secretary use any official device, mark, or certificate, or simulation thereof, or alter, detach, deface, or destroy any official device, mark, or certificate;

(3) contrary to the regulations prescribed by the Secretary, fail to use, or to detach, deface, or destroy any official device, mark, or certificate;

(4) knowingly possess, without promptly notifying the Secretary or his representative, any official device or any counterfeit, simulated, forged, or improperly altered official certificate or any device or label or any carcass of any poultry, or part or product thereof, bearing any counterfeit, simulated, forged, or improperly altered official mark;

(5) knowingly make any false statement in any shipper's certificate or other nonofficial or official certificate provided for in the regulations prescribed by the Secretary; or

(6) knowingly represent that any article has been inspected and passed, or exempted, under this chapter when, in fact, it has respectively, not been so inspected and passed, or exempted.

(Pub. L. 85-172, § 9, Aug. 28, 1957, 71 Stat. 445; Pub. L. 90-492, § 9, Aug. 18, 1968, 82 Stat. 800.)

AMENDMENTS

1968—Pub. L. 90-492 made revisions in form and phraseology, added to the enumerated prohibited acts slaughtering poultry or processing any poultry products capable of use as human food, except in compliance with the requirements of this chapter, selling and transporting adulterated or misbranded poultry products or uninspected poultry products, adulterating or misbranding poultry products while they are being transported in commerce or held for sale after such transportation, treating carcasses not in accordance with regulations promulgated by the Secretary, possessing, without notifying the Secretary, any official device or any counterfeit, simulated, etc., official certificate, or any device or label bearing any counterfeit, simulated, etc., official mark, and making false representations and statements, and clarified application to brand manufacturers and printers of existing provisions prohibiting the counterfeiting of official marks, labels, or certificates.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment of pars. (a)(1), (a)(2)(B), (a)(4), (a)(5), (b) and (c) of this section by Pub. L. 90-492 effective Aug. 18, 1968, see section 20 of Pub. L. 90-492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

Amendment of pars. (a)(2)(A), and (a)(3) of this section by Pub. L. 90-492 effective upon the expiration of sixty days after Aug. 18, 1968, see section 20(a) of Pub. L. 90-492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 461 of this title.

§ 459. Compliance by all establishments

No establishment processing poultry or poultry products for commerce otherwise subject to this chapter shall process any poultry or poultry product except in compliance with the requirements of this chapter.

(Pub. L. 85-172, § 10, Aug. 28, 1957, 71 Stat. 446; Pub. L. 90-492, § 10, Aug. 18, 1968, 82 Stat. 801.)

AMENDMENTS

1968—Pub. L. 90-492 substituted "otherwise subject to this chapter" for "in or for marketing in a designated major consuming area".

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90-492 effective Aug. 18, 1968, see section 20 of Pub. L. 90-492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 461 of this title.

§ 460. Miscellaneous activities subject to regulation

(a) Prohibition of inspection of articles not intended for use as human food; denaturation or other identification prior to distribution in commerce; inedible articles

Inspection shall not be provided under this chapter at any establishment for the slaughter of poultry or the processing of any carcasses or parts or products of poultry, which are not intended for use as human food, but such articles shall, prior to their offer for sale or transportation in commerce, unless naturally inedible by humans, be denatured or otherwise identified as prescribed by regulations of the Secretary to deter their use for human food. No person shall buy, sell, transport, or offer for sale or transportation, or receive for transportation, in commerce, or import, any poultry carcasses or parts or products thereof which are not intended for use as human food unless they are denatured or otherwise identified as required by the regulations of the Secretary or are naturally inedible by humans.

(b) Recordkeeping requirements; persons liable; scope of disclosure; access to places of business; examination of records, facilities, and inventories; copies; samples

The following classes of persons shall, for such period of time as the Secretary may by regulations prescribe, not to exceed two years unless otherwise directed by the Secretary for good cause shown, keep such records as are properly necessary for the effective enforcement of this chapter in order to insure against adulterated or misbranded poultry products for the American consumer; and all persons subject to such requirements shall, at all reasonable times, upon notice by a duly authorized representative of the Secretary, afford such representative access to their places of business and opportunity to examine the facilities, inventory, and records thereof, to copy all such records, and to take reasonable samples of their inventory upon payment of the fair market value therefor—

(1) Any person that engages in the business of slaughtering any poultry or processing,

freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any poultry, for commerce, for use as human food or animal food;

(2) Any person that engages in the business of buying or selling (as poultry products brokers, wholesalers or otherwise), or transporting, in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any poultry;

(3) Any person that engages in business, in or for commerce, as a renderer, or engages in the business of buying, selling, or transporting, in commerce, or importing, any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter.

(c) Registration of business, name of person, and trade names

No person shall engage in business, in or for commerce, as a poultry products broker, renderer, or animal food manufacturer, or engage in business in commerce as a wholesaler of any carcasses, or parts or products of the carcasses, of any poultry, whether intended for human food or other purposes, or engage in business as a public warehouseman storing any such articles in or for commerce, or engage in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased poultry, or parts of the carcasses of any poultry that died otherwise than by slaughter, unless when required by regulations of the Secretary, he has registered with the Secretary his name, and the address of each place of business at which, and all trade names under which, he conducts such business.

(d) Regulation of transactions, transportation, or importation of dead, dying, disabled or diseased poultry or carcasses to prevent use as human food

No person engaged in the business of buying, selling, or transporting in commerce, or importing, dead, dying, disabled, or diseased poultry, or any parts of the carcasses of any poultry that died otherwise than by slaughter, shall buy, sell, transport, offer for sale or transportation, or receive for transportation, in commerce, or import, any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter, unless such transaction, transportation or importation is made in accordance with such regulations as the Secretary may prescribe to assure that such poultry, or the unwholesome parts or products thereof, will be prevented from being used for human food.

(e) Federal provisions applicable to State or Territorial business transactions of a local nature and not subject to local authority

The authority conferred on the Secretary by paragraph (b), (c), or (d) of this section with respect to persons engaged in the specified kinds of business in or for commerce may be exercised with respect to persons engaged, in any State or organized territory, in such kinds of business but not in or for commerce, whenever the Secretary determines, after consultation with an appropriate advisory committee provided for in section 454 of this title, that the State or territory does not have at least equal authority under its laws or such authority is not exercised in a manner to effectuate the purposes of this chapter, including the State or territory providing for the Secretary or his representative being afforded access to such places of business and the facilities, inventories, and records thereof, and the taking of reasonable samples, where he determines necessary in carrying out his responsibilities under this chapter; and in such case the provisions of paragraph (b), (c), or (d) of this section, respectively, shall apply to such persons to the same extent and in the same manner as if they were engaged in such business in or for commerce and the transactions involved were in commerce.

(Pub. L. 85–172, § 11, Aug. 28, 1957, 71 Stat. 446; Pub. L. 90–492, § 11, Aug. 18, 1968, 82 Stat. 801.)

AMENDMENTS

1968—Pub. L. 90–492 designated existing provisions as par. (b), added pars. (a), and (c) to (e), and in par. (b), as so designated, extended the types of persons required to maintain records necessary for the enforcement of this chapter, required such persons to give representatives of the Secretary access to their places of business, and opportunity to examine records, facilities, and inventories and to copy records and take inventory samples upon payment.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment of pars. (a) to (c) and (e) of this section by Pub. L. 90–492 effective on Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

Addition of par. (d) of this section by Pub. L. 90–492 effective upon the expiration of sixty days after Aug. 18, 1968, see section 20(c) of Pub. L. 90–492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 461, 467e of this title.

§ 461. Offenses and punishment

(a) Violations; liability of agents, employees, and employers

Any person who violates the provisions of section 458, 459, 460, 463, or 466 of this title shall be fined not more than $1,000 or imprisoned not more than one year, or both; but if such violation involves intent to defraud, or any distribution or attempted distribution of an article that is adulterated (except as defined in section 453(g)(8) of this title), such person shall be fined not more than $10,000 or imprisoned not more than three years, or both. When construing or enforcing the provisions of said sections the act, omission, or failure of any person acting for or employed by any individual, partnership, corporation, or association within the scope of his employment or office shall in every case be deemed the act, omission, or failure of such individual, partnership, corporation, or association, as well as of such person.

(b) Liability of carrier

No carrier shall be subject to the penalties of this chapter, other than the penalties for violation of section 460 of this title, by reason of his receipt, carriage, holding, or delivery, in the usual course of business, as a carrier, of poultry

or poultry products, owned by another person unless the carrier has knowledge, or is in possession of facts which would cause a reasonable person to believe that such poultry or poultry products were not inspected or marked in accordance with the provisions of this chapter or were otherwise not eligible for transportation under this chapter or unless the carrier refuses to furnish on request of a representative of the Secretary the name and address of the person from whom he received such poultry or poultry products, and copies of all documents, if any there be, pertaining to the delivery of the poultry or poultry products to such carrier.

(c) Assaulting, resisting, or impeding certain persons; murder; punishments

Any person who forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any person while engaged in or on account of the performance of his official duties under this chapter shall be fined not more than $5,000 or imprisoned not more than three years, or both. Whoever, in the commission of any such acts, uses a deadly or dangerous weapon, shall be fined not more than $10,000 or imprisoned not more than ten years, or both. Whoever kills any person while engaged in or on account of the performance of his official duties under this chapter shall be punished as provided under sections 1111 and 1114 of title 18.

(Pub. L. 85–172, § 12, Aug. 28, 1957, 71 Stat. 446; Pub. L. 90–492, § 12, Aug. 18, 1968, 82 Stat. 802.)

AMENDMENTS

1968—Par. (a). Pub. L. 90–492, § 12(a), added the reference to violations of section 463 of this title, and substituted provisions that violators of the enumerated sections shall be fined not more than $1,000 or imprisoned not more than one year, or both, but that in cases involving intent to defraud, or any distribution or attempt to distribute adulterated articles, except as defined in section 453(g) of this title, the violators shall be fined not more than $10,000 or imprisoned not more than three years, or both, for provisions that violators shall be guilty of a misdemeanor and subject to imprisonment for not more than six months or a fine of not more than $3,000, or both, with increased fines and imprisonment for any subsequent violations.

Par. (b). Pub. L. 90–492, § 12(b), substituted "of poultry" for "of slaughtered poultry", "such poultry" for "such slaughtered poultry", and "otherwise not eligible" for "not otherwise eligible", and added the provision that no carrier shall be subject to punishment unless the carrier refuses to furnish the name and address of the person from whom he received such poultry or poultry products, and copies of any documents pertaining to the delivery of the poultry or poultry products to such carrier.

Par. (c). Pub. L. 90–492, § 12(c), added par. (c).

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 454 of this title.

§ 462. Reporting of violations; notice; opportunity to present views

Before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given reasonable notice of the alleged violation and opportunity to present his views orally or in writing with regard to such contemplated proceeding. Nothing in this chapter shall be construed as requiring the Secretary to report for criminal prosecution violations of this chapter whenever he believes that the public interest will be adequately served and compliance with the chapter obtained by a suitable written notice or warning.

(Pub. L. 85–172, § 13, Aug. 28, 1957, 71 Stat. 447.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 454 of this title.

§ 463. Rules and regulations

(a) Storage and handling of poultry products; violation of regulations

The Secretary may by regulations prescribe conditions under which poultry products capable of use as human food, shall be stored or otherwise handled by any person engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, or importing, such articles, whenever the Secretary deems such action necessary to assure that such articles will not be adulterated or misbranded when delivered to the consumer. Violation of any such regulation is prohibited.

(b) Other necessary rules and regulations

The Secretary shall promulgate such other rules and regulations as are necessary to carry out the provisions of this chapter.

(c) Oral presentation of views

In applying the provisons of section 553(c) of title 5 to proposed rule making under this chapter, an opportunity for the oral presentation of views shall be accorded all interested persons.

(Pub. L. 85–172, § 14, Aug. 28, 1957, 71 Stat. 447; Pub. L. 90–492, § 13, Aug. 18, 1968, 82 Stat. 803.)

AMENDMENTS

1968—Pub. L. 90–492 designated existing provisions as par. (b), added pars. (a) and (c), and in par. (b), as so designated, substituted "such other rules" for "such rules".

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 461 of this title.

§ 464. Exemptions

(a) Persons exempted

The Secretary shall, by regulation and under such conditions as to sanitary standards, practices, and procedures as he may prescribe, exempt from specific provisions of this chapter—

(1) retail dealers with respect to poultry products sold directly to consumers in individual retail stores, if the only processing operation performed by such retail dealers is the

cutting up of poultry products on the premises where such sales to consumers are made;

(2) for such period of time as the Secretary determines that it would be impracticable to provide inspection and the exemption will aid in the effective administration of this chapter, any person engaged in the processing of poultry or poultry products for commerce and the poultry or poultry products processed by such person: *Provided, however,* That no such exemption shall continue in effect on and after January 1, 1970; and

(3) persons slaughtering, processing, or otherwise handling poultry or poultry products which have been or are to be processed as required by recognized religious dietary laws, to the extent that the Secretary determines necessary to avoid conflict with such requirements while still effectuating the purposes of this chapter.

(b) Territorial exemption

The Secretary may, under such sanitary conditions as he may by regulations prescribe, exempt from the inspection requirements of this chapter the slaughter of poultry, and the processing of poultry products, by any person in any Territory not organized with a legislative body, solely for distribution within such Territory, when the Secretary determines that it is impracticable to provide such inspection within the limits of funds appropriated for administration of this chapter and that such exemption will aid in the effective administration of this chapter.

(c) Personal slaughtering; custom slaughtering; name and address of the poultry producer or processor in lieu of other labeling requirements; small enterprises; slaughterers or processors of specified number of turkeys or equivalent number of poultry of all species; poultry producers raising poultry on own farms

(1) The Secretary shall, by regulation and under such conditions, including sanitary standards, practices, and procedures, as he may prescribe, exempt from specific provisions of this chapter—

(A) the slaughtering by any person of poultry of his own raising, and the processing by him and transportation in commerce of the poultry products exclusively for use by him and members of his household and his nonpaying guests and employees;

(B) the custom slaughter by any person of poultry delivered by the owner thereof for such slaughter, and the processing by such slaughterer and transportation in commerce of the poultry products exclusively for use, in the household of such owner, by him and members of his household and his nonpaying guests and employees: *Provided,* That such custom slaughterer does not engage in the business of buying or selling any poultry products capable of use as human food;

(C) the slaughtering and processing of poultry products in any State or Territory or the District of Columbia by any poultry producer on his own premises with respect to sound and healthy poultry raised on his premises and the distribution by any person solely within such jurisdiction of the poultry products derived from such operations, if, in lieu of other labeling requirements, such poultry products are identified with the name and address of such poultry producer, and if they are not otherwise misbranded, and are sound, clean, and fit for human food when so distributed; and

(D) the slaughtering of sound and healthy poultry or the processing of poultry products of such poultry in any State or territory or the District of Columbia by any poultry producer or other person for distribution by him solely within such jurisdiction directly to household consumers, restaurants, hotels, and boarding houses, for use in their own dining rooms, or in the preparation of meals for sales direct to consumers, if, in lieu of other labeling requirements, such poultry products are identified with the name and address of the processor, and if they are not otherwise misbranded and are sound, clean, and fit for human food when distributed by such processor.

The exemptions provided for in clauses (C) and (D) above shall not apply if the poultry producer or other person engages in the current calendar year in the business of buying or selling any poultry or poultry products other than as specified in such clauses.

(2) In addition to the specific exemptions provided herein, the Secretary shall, when he determines that the protection of consumers from adulterated or misbranded poultry products will not be impaired by such action, provide by regulation, consistent with subparagraph (3), for the exemption of the operation and products of small enterprises (including poultry producers), not exempted under subparagraph (1), which are engaged in any State or Territory or the District of Columbia in slaughtering and/or cutting up poultry for distribution as carcasses or parts thereof solely for distribution within such jurisdiction, from such provisions of this chapter as he deems appropriate, while still protecting the public from adulterated or misbranded products, under such conditions, including sanitary requirements, as he shall prescribe to effectuate the purposes of this chapter.

(3) No exemption under subparagraph (1)(C) or (D) or subparagraph (2) shall apply to any poultry producer or other person who slaughters or processes the products of more than 5,000 turkeys or an equivalent number of poultry of all species in the current calendar year (four birds of other species being deemed the equivalent of one turkey).

(4) The provisions of this chapter shall not apply to poultry producers with respect to poultry of their own raising on their own farms if (i) such producers slaughter not more than 250 turkeys, or not more than an equivalent number of birds of all species during the calendar year for which this exemption is being determined (four birds of other species being deemed the equivalent of one turkey); (ii) such poultry producers do not engage in buying or selling poultry products other than those produced from poultry raised on their own farms; and (iii) none of such poultry moves in commerce (as defined in section 453(a) of this title).

(d) Applicability of adulteration and misbranding provisions to articles exempted from inspection

The adulteration and misbranding provisions of this chapter, other than the requirement of the inspection legend, shall apply to articles which are exempted from inspection under this section, except as otherwise specified under paragraphs (a) and (c).

(e) Suspension or termination of exemption

The Secretary may by order suspend or terminate any exemption under this section with respect to any person whenever he finds that such action will aid in effectuating the purposes of this chapter.

(Pub. L. 85–172, § 15, Aug. 28, 1957, 71 Stat. 447; Pub. L. 90–492, § 14, Aug. 18, 1968, 82 Stat. 803.)

AMENDMENTS

1968—Par. (a). Pub. L. 90–492, § 14(a), (b), redesignated former supars. (2)–(4) as (1)–(3), respectively, and in subpar. (2), as so redesignated, substituted "January 1, 1970" for "July 1, 1960". Former subpar. (1), which exempted poultry producers with respect to poultry of their own raising on their own farms which they sold directly to household consumers, hotels, etc., for use in their own dining rooms or in the preparation of meals for sales direct to consumers only, provided that such producers did not engage in buying or selling poultry products other than those produced from poultry raised on their own farms, was struck out.

Par. (b). Pub. L. 90–492, § 14(c), added par. (b). Former par. (b) was redesignated as (e).

Pars. (c), (d). Pub. L. 90–492, § 14(c), added pars. (c) and (d).

Par. (e). Pub. L. 90–492, § 14(c), redesignated former par. (b) as (e).

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective upon the expiration of sixty days after Aug. 18, 1968, see section 20(b) of Pub. L. 90–492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 454 of this title.

§ 465. Limitations upon entry of poultry products and other materials into official establishments

The Secretary may limit the entry of poultry products and other materials into any official establishment, under such conditions as he may prescribe to assure that allowing the entry of such articles into such inspected establishments will be consistent with the purposes of this chapter.

(Pub. L. 85–172, § 16, Aug. 28, 1957, 71 Stat. 448; Pub. L. 90–492, § 15, Aug. 18, 1968, 82 Stat. 805.)

AMENDMENTS

1968—Pub. L. 90–492 substituted provisions authorizing the Secretary to limit the entry of poultry products and other materials into any official establishment for provisions that any person distributing unwholesome or adulterated exempted poultry or poultry products intended for human consumption shall be guilty of a misdemeanor and subject to penalties upon conviction thereof.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90–492 effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 454 of this title.

§ 466. Imports

(a) Compliance with standards and regulations; status after importation

No slaughtered poultry, or parts or products thereof, of any kind shall be imported into the United States unless they are healthful, wholesome, fit for human food, not adulterated, and contain no dye, chemical, preservative, or ingredient which renders them unhealthful, unwholesome, adulterated, or unfit for human food and unless they also comply with the rules and regulations made by the Secretary of Agriculture to assure that imported poultry or poultry products comply with the standards provided for in this chapter. All imported, slaughtered poultry, or parts or products thereof, shall after entry into the United States in compliance with such rules and regulations be deemed and treated as domestic slaughtered poultry, or parts or products thereof, within the meaning and subject to the provisions of this chapter and the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], and Acts amendatory of, supplemental to, or in substitution for such chapter and Act.

(b) Rules and regulations; destruction and exportation of refused imports

The Secretary of Agriculture is authorized to make rules and regulations to carry out the purposes of this section and in such rules and regulations the Secretary of Agriculture may prescribe the terms and conditions for the destruction of all slaughtered poultry, or parts or products thereof, offered for entry and refused admission into the United States unless such slaughtered poultry, or parts or products thereof, be exported by the consignee within the time fixed therefor in such rules and regulations.

(c) Storage, cartage and labor charges for imports refused admission

All charges for storage, cartage, and labor with respect to any product which is refused admission pursuant to this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any other products imported thereafter by or for such owner or consignee.

(Pub. L. 85–172, § 17, Aug. 28, 1957, 71 Stat. 448.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 461 of this title.

§ 467. Inspection services

(a) Refusal or withdrawal; hearing; business unfitness based upon certain convictions; persons responsibly connected with the business

The Secretary may (for such period, or indefinitely, as he deems necessary to effectuate the purposes of this chapter) refuse to provide, or withdraw, inspection service under this chapter with respect to any establishment if he determines, after opportunity for a hearing is accorded to the applicant for, or recipient of, such service, that such applicant or recipient is unfit to engage in any business requiring inspection upon this chapter because the applicant or recipient or anyone responsibly connected with the applicant or recipient, has been convicted, in any Federal or State court, within the previous ten years of (1) any felony or more than one misdemeanor under any law based upon the acquiring, handling, or distributing of adulterated, mislabeled, or deceptively packaged food or fraud in connection with transactions in food; or (2) any felony, involving fraud, bribery, extortion, or any other act or circumstances indicating a lack of the integrity needed for the conduct of operations affecting the public health. For the purpose of this paragraph a person shall be deemed to be responsibly connected with the business if he was a partner, officer, director, holder, or owner of 10 per centum or more of its voting stock or employee in a managerial or executive capacity.

(b) Hearing to determine validity of withdrawal or refusal of inspection services; continuation of withdrawal or refusal

Upon the withdrawal of inspection service from any official establishment for failure to destroy condemned poultry products as required under section 455 of this title, or other failure of an official establishment to comply with the requirements as to premises, facilities, or equipment, or the operation thereof, as provided in section 456 of this title, or the refusal of inspection service to any applicant therefor because of failure to comply with any requirements under section 456 of this title, the applicant for, or recipient of, the service shall, upon request, be afforded opportunity for a hearing with respect to the merits or validity of such action; but such withdrawal or refusal shall continue in effect unless otherwise ordered by the Secretary.

(c) Finality and conclusiveness of determination; judicial review; record

The determination and order of the Secretary when made after opportunity for hearing, with respect to withdrawal or refusal of inspection service under this chapter shall be final and conclusive unless the affected applicant for, or recipient of, inspection service files application for judicial review within thirty days after the effective date of such order in the United States Court of Appeals as provided in section 457 of this title. Judicial review of any such order shall be upon the record upon which the determination and order are based. The provisions of section 194 of title 7 shall be applicable to appeals taken under this section.

(Pub. L. 85-172, § 18, Aug. 28, 1957, 71 Stat. 448; Pub. L. 90-492, § 16, Aug. 18, 1968, 82 Stat. 805.)

AMENDMENTS

1968—Par. (a). Pub. L. 90-492 substituted provisions authorizing the Secretary to refuse or withdraw inspection services subsequent to a hearing determining that the applicant or recipient is unfit to engage in any business requiring inspection under this chapter based upon the specified considerations, for provisions granting the Secretary exclusive jurisdiction within the scope of this chapter and exempting poultry and poultry products from the provisions of the Federal Food, Drug, and Cosmetic Act, as amended, to the extent of the application or the extension thereof of the provisions of this chapter.

Par. (b). Pub. L. 90-492 substituted provisions granting a hearing, upon request by the applicant or recipient, to determine the merits and validity of the withdrawal or refusal of inspection services and continuing such withdrawal or refusal in effect, unless otherwise ordered by the Secretary, for provisions authorizing the Secretary to cooperate with other branches of government and with state agencies and to conduct examinations, investigations, and inspections through any officer or employee of a state commissioned by the Secretary for such purpose.

Par. (c). Pub. L. 90-492 added par. (c).

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90-492 effective Aug. 18, 1968, see section 20 of Pub. L. 90-492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 467c of this title.

§ 467a. Administrative detention; duration; pending judicial proceedings; notification of government authorities; release; removal of official marks

Whenever any poultry product, or any product exempted from the definition of a poultry product, or any dead, dying, disabled, or diseased poultry is found by any authorized representative of the Secretary upon any premises where it is held for purposes of, or during or after distribution in, commerce or otherwise subject to this chapter, and there is reason to believe that any such article is adulterated or misbranded and is capable of use as human food, or that it has not been inspected, in violation of the provisions of this chapter or of any other Federal law or the laws of any State or Territory, or the District of Columbia, or that it has been or is intended to be, distributed in violation of any such provisions, it may be detained by such representative for a period not to exceed twenty days, pending action under section 467b of this title or notification of any Federal, State, or other governmental authorities having jurisdiction over such article or poultry, and shall not be moved by any person, from the place at which it is located when so detained, until released by such representative. All official marks may be required by such representative to be removed from such article or poultry before it is released unless it appears to the satisfaction of the Secretary that the article or poultry is eligible to retain such marks.

(Pub. L. 85-172, § 19, as added Pub. L. 90-492, § 17, Aug. 18, 1968, 82 Stat. 805.)

EFFECTIVE DATE

Section effective Aug. 18, 1968, see section 20 of Pub. L. 90-492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 467f of this title.

§ 467b. Seizure and condemnation

(a) Proceedings in rem; libel of information; jurisdiction; disposal by destruction or sale; proceeds into the Treasury; sales restrictions; bonds; court costs and fees, storage, and other expenses against claimants; jury trial; United States as plaintiff

Any poultry product, or any dead, dying, disabled, or diseased poultry, that is being transported in commerce or otherwise subject to this chapter, or is held for sale in the United States after such transportation, and that (1) is or has been processed, sold, transported, or otherwise distributed or offered or received for distribution in violation of this chapter, or (2) is capable of use as human food and is adulterated or misbranded, or (3) in any other way is in violation of this chapter, shall be liable to be proceeded against and seized and condemned, at any time, on a libel of information in any United States district court or other proper court as provided in section 467c of this title within the jurisdiction of which the article or poultry is found. If the article or poultry is condemned it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs and fees, and storage and other proper expenses, shall be paid into the Treasury of the United States, but the article or poultry shall not be sold contrary to the provisions of this chapter, or the laws of the jurisdiction in which it is sold: *Provided*, That upon the execution and delivery of a good and sufficient bond conditioned that the article or poultry shall not be sold or otherwise disposed of contrary to the provisions of this chapter, or the laws of the jurisdiction in which disposal is made, the court may direct that such article or poultry be delivered to the owner thereof subject to such supervision by authorized representatives of the Secretary as is necessary to insure compliance with the applicable laws. When a decree of condemnation is entered against the article or poultry and it is released under bond, or destroyed, court costs and fees, and storage and other proper expenses shall be awarded against the person, if any, intervening as claimant of the article or poultry. The proceedings in such libel cases shall conform, as nearly as may be, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

(b) Condemnation or seizure under other provisions unaffected

The provisions of this section shall in no way derogate from authority for condemnation or seizure conferred by other provisions of this chapter, or other laws.

(Pub. L. 85–172, § 20, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 806.)

EFFECTIVE DATE

Section effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 467a of this title.

§ 467c. Federal court jurisdiction of enforcement and injunction proceedings and other kinds of cases; limitations; United States as plaintiff; subpenas

The United States district courts, the District Court of Guam, the District Court of the Virgin Islands, the highest court of American Samoa, and the United States courts of the other territories, are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this chapter, and shall have jurisdiction in all other kinds of cases arising under this chapter, except as provided in section 457(d) or 467 of this title. All proceedings for the enforcement or to restrain violations of this chapter shall be by and in the name of the United States. Subpenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding.

(Pub. L. 85–172, § 21, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 806.)

EFFECTIVE DATE

Section effective Aug. 18, 1968, see section 20 of Pub. L. 90–492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 467b, 467d of this title.

§ 467d. Administration and enforcement; applicability of penalty provisions; conduct of inquiries; power and jurisdiction of courts

For the efficient administration and enforcement of this chapter, the provision (including penalties) of sections 46, 48, 49 and 50 of title 15 (except paragraphs (c) through (h) of section 46 of title 15 and the last paragraph of section 49 of title 15), and the provisions of section 409(*l*) of title 47, are made applicable to the jurisdiction, powers, and duties of the Secretary in administering and enforcing the provisions of this chapter and to any person with respect to whom such authority is exercised. The Secretary, in person or by such agents as he may designate, may prosecute any inquiry necessary to his duties under this chapter in any part of the United States, and the powers conferred by said sections 49 and 50 of title 15 on the district courts of the United States may be exercised for the purposes of this chapter by any court designated in section 467c of this title.

(Pub. L. 85–172, § 22, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 807.)

REFERENCES IN TEXT

The last paragraph of section 49 of title 15, and the provisions of section 409(*l*) of title 47, referred to in text, which related to immunity of witnesses, were repealed by sections 211 and 242 of Pub. L. 91–452, Oct. 15, 1970, title II, 84 Stat. 929, 930, respectively. For current provisions relating to immunity of witnesses,

see section 6001 et seq. of Title 18, Crimes and Criminal Procedure.

EFFECTIVE DATE

Section effective Aug. 18, 1968, see section 20 of Pub. L. 90-492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 454 of this title.

§ 467e. Non-Federal jurisdiction of Federally regulated matters; prohibition of additional or different requirements for establishments with inspection services and as to marking, labeling, packaging, and ingredients; recordkeeping and related requirements; concurrent jurisdiction over distribution for human food purposes of adulterated or misbranded and imported articles; other matters

Requirements within the scope of this chapter with respect to premises, facilities and operations of any official establishment which are in addition to, or different than those made under this chapter may not be imposed by any State or Territory or the District of Columbia, except that any such jurisdiction may impose recordkeeping and other requirements within the scope of paragraph (b) of section 460 of this title, if consistent therewith, with respect to any such establishment. Marking, labeling, packaging, or ingredient requirements (or storage or handling requirements found by the Secretary to unduly interfere with the free flow of poultry products in commerce) in addition to, or different than, those made under this chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any official establishment in accordance with the requirements under this chapter, but any State or Territory or the District of Columbia may, consistent with the requirements under this chapter exercise concurrent jurisdiction with the Secretary over articles required to be inspected under this chapter for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles which are not at such an establishment, after their entry into the United States. This chapter shall not preclude any State or Territory or the District of Columbia from making requirement or taking other action, consistent with this chapter with respect to any other matters regulated under this chapter.

(Pub. L. 85-172, § 23, as added Pub. L. 90-492, § 17, Aug. 18, 1968, 82 Stat. 807.)

EFFECTIVE DATE

Section effective Aug. 18, 1968, see section 20 of Pub. L. 90-492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

§ 467f. Federal Food, Drug, and Cosmetic Act applications

(a) Exemptions; authorities under food, drug, and cosmetic provisions unaffected

Poultry and poultry products shall be exempt from the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et. seq.] to the extent of the application or extension thereto of the provisions of this chapter, except that the provisions of this chapter shall not derogate from any authority conferred by the Federal Food, Drug, and Cosmetic Act prior to August 18, 1968.

(b) Enforcement proceedings; detainer authority of representatives of Secretary of Health, Education, and Welfare

The detainer authority conferred by section 467a of this title shall apply to any authorized representative of the Secretary of Health, Education, and Welfare for purposes of the enforcement of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] with respect to any poultry carcass, or part or product thereof, that is outside any official establishment, and for such purposes the first reference to the Secretary in section 467a of this title shall be deemed to refer to the Secretary of Health, Education, and Welfare.

(Pub. L. 85-172, § 24, as added Pub. L. 90-492, § 17, Aug. 18, 1968, 82 Stat. 807.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in text, is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables volume.

EFFECTIVE DATE

Section effective Aug. 18, 1968, see section 20 of Pub. L. 90-492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

§ 468. Cost of inspection; overtime

The cost of inspection rendered under the requirements of this chapter, shall be borne by the United States, except that the cost of overtime and holiday work performed in establishments subject to the provisions of this chapter at such rates as the Secretary may determine shall be borne by such establishments. Sums received by the Secretary in reimbursement for sums paid out by him for such premium pay work shall be available without fiscal year limitation to carry out the purposes of this section.

(Pub. L. 85-172, § 25, formerly § 19, Aug. 28, 1957, 71 Stat. 448, renumbered Pub. L. 90-492, § 17, Aug. 18, 1968, 82 Stat. 805.)

§ 469. Authorization of appropriations

There is authorized to be appropriated such sums as are necessary to carry out the provisions of this chapter.

(Pub. L. 85-172, § 26, formerly § 20, Aug. 28, 1957, 71 Stat. 449, renumbered Pub. L. 90-492, § 17, Aug. 18, 1968, 82 Stat. 805.)

§ 470. Reports to Congress

The Secretary shall annually report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate with respect to the slaughter of poultry subject to this chapter, and the preparation, storage, handling, and distribution of poultry parts, poultry products, and inspection of establishments operated in connection therewith, including the operations under and the effectiveness of this chapter.

(Pub. L. 85-172, § 27, as added Pub. L. 90-492, § 17, Aug. 18, 1968, 82 Stat. 807, and amended S. Res. 4, Feb. 4, 1977.)

CHANGE OF NAME

The Committee on Agriculture and Forestry of the Senate was abolished and replaced by the Committee on Agriculture, Nutrition, and Forestry of the Senate, effective Feb. 11, 1977. See Rule XXV of the Standing Rules of the Senate, as amended by Senate Resolution 4 (popularly cited as the "Committee System Reorganization Amendments of 1977"), approved Feb. 4, 1977.

EFFECTIVE DATE

Section effective Aug. 18, 1968, see section 20 of Pub. L. 90-492, set out as an Effective Date of 1968 Amendment note under section 451 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 454 of this title.

CHAPTER 11—MANUFACTURE OF NARCOTIC DRUGS

§§ 501 to 517. Repealed. Pub. L. 91-513, title III, § 1101(a)(10), Oct. 27, 1970, 84 Stat. 1292

Sections, Pub. L. 86-429, Apr. 22, 1960, 74 Stat. 55, provided for the licensing and control of the manufacture of all narcotic drugs and was known as the "Narcotic Manufacturing Act of 1960". Sections 1 to 3 and 5 to 22 of said Pub. L. 86-429 were classified respectively to sections 501, 501 notes, and 502 to 517 of this title. Section 4 of Pub. L. 86-429 was classified to sections 4702, 4731, and 4731 note of Title 26, Internal Revenue Code. See section 801 et seq. of this title.

EFFECTIVE DATE OF REPEAL

Repeal of sections effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, see section 1105(a) of Pub. L. 91-513, set out as a note under section 951 of this title. For provisions postponing such effective date if the Attorney General postpones the effective date of section 826 of this title, see section 1105(c) of Pub. L. 91-513, set out as an Effective Date note under section 951 of this title.

SAVINGS PROVISIONS

Prosecutions for any violation of law occurring, and civil seizures or forfeitures and injunctive proceedings commenced, prior to the effective date of repeal of these sections by section 1101 of Pub. L. 91-513 not to be affected or abated by reason thereof, see section 1103 of Pub. L. 91-513, set out as a Savings Provisions note under sections 171 to 174 of this title.

CHAPTER 12—MEAT INSPECTION

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This chapter is referred to in sections 321, 392 of this title; title 7 section 394.

SUBCHAPTER I—INSPECTION REQUIREMENTS; ADULTERATION AND MISBRANDING

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in sections 641, 661, 671, 672, 673, 678 of this title.

§ 601. Definitions

As used in this chapter, except as otherwise specified, the following terms shall have the meanings stated below:

(a) The term "Secretary" means the Secretary of Agriculture of the United States or his delegate.

(b) The term "firm" means any partnership, association, or other unincorporated business organization.

(c) The term "meat broker" means any person, firm, or corporation engaged in the business of buying or selling carcasses, parts of carcasses, meat, or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines on commission, or otherwise negotiating purchases or sales of such articles other than for his own account or as an employee of another person, firm, or corporation.

(d) The term "renderer" means any person, firm, or corporation engaged in the business of rendering carcasses or parts or products of the carcasses, of cattle, sheep, swine, goats, horses, mules, or other equines, except rendering conducted under inspection or exemption under this subchapter.

(e) The term "animal food manufacturer" means any person, firm, or corporation engaged in the business of manufacturing or processing animal food derived wholly or in part from carcasses, or parts of products of the carcasses, of cattle, sheep, swine, goats, horses, mules, or other equines.

(f) The term "State" means any State of the United States and the Commonwealth of Puerto Rico.

(g) The term "Territory" means Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States, excluding the Canal Zone.

(h) The term "commerce" means commerce between any State, any Territory, or the District of Columbia, and any place outside thereof; or within any Territory not organized with a legislative body, or the District of Columbia.

(i) The term "United States" means the States, the District of Columbia, and the Territories of the United States.

(j) The term "meat food product" means any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products. This term as applied to food products of equines shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

(k) The term "capable of use as human food" shall apply to any carcass, or part or product of a carcass, of any animal, unless it is denatured or otherwise identified as required by regulations prescribed by the Secretary to deter its use as human food, or it is naturally inedible by humans.

(*l*) The term "prepared" means slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

(m) The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)(A) if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;

(B) if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title,

(C) if it bears or contains any food additive which is unsafe within the meaning of section 348 of this title,

(D) if it bears or contains any color additive which is unsafe within the meaning of section 376 of this title: *Provided*, That an article which is not adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in establishments at which inspection is maintained under this subchapter;

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) if it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title;

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or

strength, or make it appear better or of greater value than it is; or

(9) if it is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance.

(n) The term "misbranded" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) if its labeling is false or misleading in any particular;

(2) if it is offered for sale under the name of another food;

(3) if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter, the name of the food imitated;

(4) if its container is so made, formed, or filled as to be misleading;

(5) if in a package or other container unless it bears a label showing (A) the name and place of business of the manufacturer, packer, or distributor; and (B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided,* That under clause (B) of this subparagraph (5), reasonable variations may be permitted, and exemptions as to small packages may be established, by regulations prescribed by the Secretary;

(6) if any word, statement, or other information required by or under authority of this chapter to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) if it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations of the Secretary under section 607 of this title unless (A) it conforms to such definition and standard, and (B) its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) if it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by regulations of the Secretary under section 607 of this title, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(9) if it is not subject to the provisions of subparagraph (7), unless its label bears (A) the common or usual name of the food, if any there be, and (B) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings may, when authorized by the Secretary, be designated as spices, flavorings, and colorings without naming each: *Provided,* That to the extent that compliance with the requirements of clause (B) of this subparagraph (9) is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary;

(10) if it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary, after consultation with the Secretary of Health, Education, and Welfare, determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses;

(11) if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided,* That, to the extent that compliance with the requirements of this subparagraph (11) is impracticable, exemptions shall be established by regulations promulgated by the Secretary; or

(12) if it fails to bear, directly thereon or on its container, as the Secretary may by regulations prescribe, the inspection legend and, unrestricted by any of the foregoing, such other information as the Secretary may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

(o) The term "label" means a display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

(p) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(q) The term "Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]" means the Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

(r) The terms "pesticide chemical," "food additive," "color additive," and "raw agricultural commodity" shall have the same meanings for purposes of this chapter as under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(s) The term "official mark" means the official inspection legend or any other symbol prescribed by regulations of the Secretary to identify the status of any article or animal under this chapter.

(t) The term "official inspection legend" means any symbol prescribed by regulations of the Secretary showing that an article was inspected and passed in accordance with this chapter.

(u) The term "official certificate" means any certificate prescribed by regulations of the Secretary for issuance by an inspector or other person performing official functions under this chapter.

(v) The term "official device" means any device prescribed or authorized by the Secretary for use in applying any official mark.

(Mar. 4, 1907, ch. 2907, title I, § 1, as added Dec. 15, 1967, Pub. L. 90-201, § 2, 81 Stat. 584.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in pars. (q) and (r), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables volume.

EFFECTIVE DATE

Section 20 of Pub. L. 90-201 provided that:

"This Act [see Short Title note below] shall become effective upon enactment [Dec. 15, 1967] except as provided in paragraphs (a) through (d):

"(a) The provisions of paragraph (b)(1) and (c) of section 10 and the provisions of section 20 of the Federal Meat Inspection Act, as amended by sections 7 and 10 of this Act [sections 610 and 620 of this title], and the provisions of section 18 of this Act repealing paragraph (b) of section 306 of the Tariff Act of 1930 [section 1306(b) of Title 19, Customs Duties], shall become effective upon the expiration of sixty days after enactment [Dec. 15, 1967], hereof.

"(b) The provisions of title I of the Federal Meat Inspection Act, as amended by this Act [this subchapter], shall become effective with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof upon the expiration of sixty days after enactment [Dec. 15, 1967] hereof.

"(c) Section 11 of this Act, amending section 23, of the Federal Meat Inspection Act [section 623 of this title], shall become effective upon the expiration of sixty days after enactment hereof [Dec. 15, 1967].

"(d) Section 204 of the Federal Meat Inspection Act, as added by section 14 of this Act [section 644 of this title], shall become effective upon the expiration of sixty days after enactment hereof [Dec. 15, 1967]."

SHORT TITLE

Section 1 of Pub. L. 90-201 provided in part: "That this Act [which enacted sections 601, 602, 624, 641 to 645, 661, 671 to 680, and 691 of this title, amended sections 603 to 623 of this title, repealed section 96 of this title and section 1306(b) of Title 19, Customs Duties, and enacted provisions set out as notes under this section] may be cited as the 'Wholesome Meat Act'."

Section 1 of Pub. L. 90-201 provided in part that the provisions of act Mar. 4, 1907, as amended, classified to subchapters I to IV of this chapter, are designated as the "Federal Meat Inspection Act".

SEPARABILITY OF PROVISIONS

Section 19 of Pub. L. 90-201 provided that: "If any provision of this Act or of the amendments made hereby [see Short Title note above] or the application thereof to any person or circumstances is held invalid, the validity of the remainder of the Act and the remaining amendments [see Short Title note above] and of the application of such provision to other persons and circumstances shall not be affected thereby."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 607, 676 of this title; title 15 sections 2052, 2602.

ACT REFERRED TO IN OTHER SECTIONS

The Wholesome Meat Act is referred to in section 1053 of this title.

§ 602. Congressional statement of findings

Meat and meat food products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded meat or meat food products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to livestock producers and processors of meat and meat food products, as well as injury to consumers. The unwholesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower prices and complete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally. It is hereby found that all articles and animals which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

(Mar. 4, 1907, ch. 2907, title I, § 2, as added Dec. 15, 1967, Pub. L. 90-201, § 2, 81 Stat. 587.)

§ 603. Inspection of meat and meat food products; examination of animals before slaughtering; diseased animals slaughtered separately and carcasses examined

For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all cattle, sheep, swine, goats, horses, mules, and other equines before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce; and all cattle, sheep, swine, goats, horses, mules, and other equines found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine, goats, horses, mules, or other equines, and when so slaughtered the carcasses of said cattle, sheep, swine, goats, horses, mules, or other equines shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter.

(Mar. 4, 1907, ch. 2907, title I, § 3, formerly 1st par., 34 Stat. 1260, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 3, 12(a), (b), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 71 of this title.

AMENDMENTS

1967—Pub. L. 90-201, §§ 3, 12(a), (b), deleted "interstate or foreign" preceding "commerce" in two instances, substituted "Secretary shall" for "Secretary, at his discretion, may" and deleted "of Agriculture" following "Secretary", included horses, mules, and other equines, and horses, mules, or other equines in the list of animals, and substituted "adulterated" for "unsound, unhealthful, unwholesome, or otherwise unfit for human food", respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 604. Post mortem examination of carcasses and marking or labeling; destruction of carcasses condemned; reinspection

For the purposes hereinbefore set forth the Secretary shall cause to be made by inspectors appointed for that purpose a post mortem examination and inspection of the carcasses and parts thereof of all cattle, sheep, swine, goats, horses, mules, and other equines to be prepared at any slaughtering, meat-canning, salting, packing, rendering, or similar establishment in any State, Territory, or the District of Columbia as articles of commerce which are capable of use as human food; and the carcasses and parts thereof of all such animals found to be not adulterated shall be marked, stamped, tagged, or labeled as "Inspected and passed"; and said inspectors shall label, mark, stamp, or tag as "Inspected and condemned" all carcasses and parts thereof of animals found to be adulterated; and all carcasses and parts thereof thus inspected and condemned shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary may remove inspectors from any such establishment which fails to so destroy any such condemned carcass or part thereof, and said inspectors, after said first inspection, shall, when they deem it necessary, reinspect said carcasses or parts thereof to determine whether since the first inspection the same have become adulterated, and if any carcass or any part thereof shall, upon examination and inspection subsequent to the first examination and inspection, be found to be adulterated, it shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary may remove inspectors from any establishment which fails to so destroy any such condemned carcass or part thereof.

(Mar. 4, 1907, ch. 2907, title I, § 4, formerly 2nd par., 34 Stat. 1260, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 3, 4, 12(a)-(d), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 72 of this title.

AMENDMENTS

1967—Pub. L. 90-201, §§ 3, 4, 12(a) to (d), deleted "interstate or foreign" preceding "commerce" and "of Agriculture" following "Secretary" in three instances; deleted "for human consumption" preceding "at any slaughtering" and "for transportation or sale" following "District of Columbia" and inserted "which are capable of use as human food" following "commerce"; included horses, mules, and other equines in the list of animals; substituted "adulterated" for "unsound, unhealthful, unwholesome, or otherwise unfit for human food" following "'Inspected and condemned,' all carcasses and parts thereof of animals found to be" and preceding ", it shall be destroyed"; substituted "not adulterated" for "sound, healthful, wholesome, and fit for human food"; and substituted "adulterated" for "unsound, unhealthful, unwholesome, or in any way unfit for human food" preceding "and if any carcass", respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 605. Examination of carcasses brought into slaughtering or packing establishments, and of meat food products issued from and returned thereto; conditions for entry

The foregoing provisions shall apply to all carcasses or parts of carcasses of cattle, sheep, swine, goats, horses, mules, and other equines or the meat or meat products thereof which may be brought into any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, and such examination and inspection shall be had before the said carcasses or parts thereof shall be allowed to enter into any department wherein the same are to be treated and prepared for meat food products; and the foregoing provisions shall also apply to all such products, which, after having been issued from any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, shall be returned to the same or to any similar establishment where such inspection is maintained. The Secretary may limit the entry of carcasses, parts of carcasses, meat and meat food products, and other materials into any establishment at which inspection under this subchapter is maintained, under such conditions as he may prescribe to assure that allowing the entry of such articles into such inspected establishments will be consistent with the purposes of this chapter.

(Mar. 4, 1907, ch. 2907, title I, § 5, formerly 3rd par., 34 Stat. 1261, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 5, 12(a), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 73 of this title.

AMENDMENTS

1967—Pub. L. 90-201, §§ 5, 12(a), limited entry of articles into establishments under such prescribed conditions as would be consistent with the purpose of this chapter and included horses, mules, and other equines in the list of animals, respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective

upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 606. Inspectors of meat food products; marks of inspection; destruction of condemned products; products for export

For the purposes hereinbefore set forth the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all meat food products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, and for the purposes of any examination and inspection and inspectors shall have access at all times, by day or night, whether the establishment be operated or not, to every part of said establishment; and said inspectors shall mark, stamp, tag, or label as "Inspected and passed" all such products found to be not adulterated; and said inspectors shall label, mark, stamp, or tag as "Inspected and condemned" all such products found adulterated, and all such condemned meat food products shall be destroyed for food purposes, as hereinbefore provided, and the Secretary may remove inspectors from any establishment which fails to so destroy such condemned meat food products: *Provided*, That subject to the rules and regulations of the Secretary the provisions of this section in regard to preservatives shall not apply to meat food products for export to any foreign country and which are prepared or packed according to the specifications or directions of the foreign purchaser, when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is to be exported; but if said article shall be in fact sold or offered for sale for domestic use or consumption then this proviso shall not exempt said article from the operation of all the other provisions of this chapter.

(Mar. 4, 1907, ch. 2907, title I, § 6, formerly 4th par., 34 Stat. 1261, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 3, 12(e), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 74 of this title.

AMENDMENTS

1967—Pub. L. 90-201, §§ 3, 12(e), deleted "interstate or foreign" preceding "commerce" and "of Agriculture" following "Secretary" in three instances, and substituted "not adulterated" for "sound, healthful, and wholesome, and which contains no dyes, chemicals, preservatives, or ingredients which render such meat or meat food products unsound, unhealthful, unwholesome, or unfit for human food" and "adulterated" for "unsound, unhealthful, and unwholesome, or which contain dyes, chemicals, preservatives, or ingredients which render such meat or meat food products unsound, unhealthful, unwholesome, or unfit for human food," respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 607. Labeling, marking, and container requirements

(a) Labeling receptacles or coverings of meat or meat food products inspected and passed; supervision by inspectors

When any meat or meat food product prepared for commerce which has been inspected as herinbefore provided and marked "Inspected and passed" shall be placed or packed in any can, pot, tin, canvas, or other receptacle or covering in any establishment where inspection under the provisions of this chapter is maintained, the person, firm, or corporation preparing said product shall cause a label to be attached to said can, pot, tin, canvas, or other receptacle or covering, under the supervision of an inspector, which label shall state that the contents thereof have been "inspected and passed" under the provisions of this chapter; and no inspection and examination of meat or meat food products deposited or inclosed in cans, tins, pots, canvas, or other receptacle or covering in any establishment where inspection under the provisions of this chapter is maintained shall be deemed to be complete until such meat or meat food products have been sealed or inclosed in said can, tin, pot, canvas, or other receptacle or covering under the supervision of an inspector.

(b) Information on articles or containers; legible form

All carcasses, parts of carcasses, meat and meat food products inspected at any establishment under the authority of this subchapter and found to be not adulterated, shall at the time they leave the establishment bear, in distinctly legible form, directly thereon or on their containers, as the Secretary may require, the information required under paragraph (n) of section 601 of this title.

(c) Labeling: type styles and sizes; definitions and standards of identity or composition; standards of fill of container; consistency of Federal and Federal-State standards

The Secretary, whenever he determines such action is necessary for the protection of the public, may prescribe: (1) the styles and sizes of type to be used with respect to material required to be incorporated in labeling to avoid false or misleading labeling in marketing and labeling any articles or animals subject to this subchapter or subchapter II of this chapter; (2) definitions and standards of identity or composition for articles subject to this subchapter and standards of fill of container for such articles not inconsistent with any such standards established under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], and there shall be consultation between the Secretary and the Secretary of Health, Education, and Welfare prior to the issuance of such standards under either Act relating to articles subject to this chapter to avoid inconsistency in such standards and possible impairment of the coordinated effective administration of these Acts. There shall also be consultation between the Secretary and an appropriate advisory committee provided for in section 661 of this title, prior to the issuance of such standards under

this chapter, to avoid, insofar as feasible, inconsistency between Federal and State standards.

(d) Sales under false or misleading name, other marking or labeling or in containers of misleading form or size; trade names, and other marking, labeling, and containers approved by Secretary

No article subject to this subchapter shall be sold or offered for sale by any person, firm, or corporation, in commerce, under any name or other marking or labeling which is false or misleading, or in any container of a misleading form or size, but established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted.

(e) Use withholding directive respecting false or misleading marking, labeling, or container; modification of false or misleading matter; hearing; withholding use pending proceedings; finality of Secretary's action: judicial review: application of section 194 of title 7

If the Secretary has reason to believe that any marking or labeling or the size or form of any container in use or proposed for use with respect to any article subject to this subchapter is false or misleading in any particular, he may direct that such use be withheld unless the marking, labeling, or container is modified in such manner as he may prescribe so that it will not be false or misleading. If the person, firm, or corporation using or proposing to use the marking, labeling or container does not accept the determination of the Secretary, such person, firm, or corporation may request a hearing, but the use of the marking, labeling, or container shall, if the Secretary so directs, be withheld pending hearing and final determination by the Secretary. Any such determination by the Secretary shall be conclusive unless, within thirty days after receipt of notice of such final determination, the person, firm, or corporation adversely affected thereby appeals to the United States court of appeals for the circuit in which such person, firm, or corporation has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit. The provisions of section 194 of title 7 shall be applicable to appeals taken under this section.

(Mar. 4, 1907, ch. 2907, title I, § 7, formerly 5th par., 34 Stat. 1262, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 3(a), 6, 81 Stat. 584, 588.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in par. (c)(2), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables volume.

Either Act and these Acts, referred to in subsec. (c)(2), mean the Federal Meat Inspection Act and the Federal Food, Drug, and Cosmetic Act. The Federal Meat Inspection Act is act Mar. 4, 1907, ch. 2907, titles I to IV, as added Dec. 15, 1967, Pub. L. 90-201, 81 Stat. 584, which are classified generally to subchapters I to IV (§ 601 et seq.) of this chapter. For complete classification of this Act to the Code, see Short Title note under section 601 of this title and Tables volume.

CODIFICATION

Section was formerly classified to section 75 of this title.

AMENDMENTS

1967—Subsec. (a). Pub. L. 90-201, §§ 3(a), 6(a), (b), deleted "interstate or foreign" preceding "commerce" and provisions prohibiting sales of meat or meat food products in interstate or foreign commerce under any false or deceptive names and permitting trade names or names which are usual to such products and are not false and deceptive and are approved by the Secretary of Agriculture, now incorporated in par. (d), and designated remaining provisions as par. (a), respectively.

Subsecs. (b) to (e). Pub. L. 90-201, § 6(c), added pars. (b) to (e).

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

CROSS REFERENCES

Federal Food, Drug, and Cosmetic Act defined, see section 601 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 601, 674 of this title.

§ 608. Sanitary inspection and regulation of slaughtering and packing establishments; rejection of adulterated meat or meat food products

The Secretary shall cause to be made, by experts in sanitation or by other competent inspectors, such inspection of all slaughtering, meat canning, salting, packing, rendering, or similar establishments in which cattle, sheep, swine, goats, horses, mules and other equines are slaughtered and the meat and meat food products thereof are prepared for commerce as may be necessary to inform himself concerning the sanitary conditions of the same, and to prescribe the rules and regulations of sanitation under which such establishments shall be maintained; and where the sanitary conditions of any such establishment are such that the meat or meat food products are rendered adulterated, he shall refuse to allow said meat or meat food products to be labeled, marked, stamped or tagged as "inspected and passed."

(Mar. 4, 1907, ch. 2907, title I, § 8, formerly 6th par., 34 Stat. 1262, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 3, 12(a), (f), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 76 of this title.

AMENDMENTS

1967—Pub. L. 90-201, §§ 3, 12(a), (f), deleted "interstate or foreign" preceding "commerce" and "of Agriculture" following "Secretary", included horses, mules, and other equines in the list of animals, and substituted "adulterated" for "unclean, unsound, unhealthful, unwholesome, or otherwise unfit for human food", respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 609. Examination of animals and food products thereof, slaughtered and prepared during nighttime

The Secretary shall cause an examination and inspection of all cattle, sheep, swine, goats, horses, mules and other equines, and the food products thereof, slaughtered and prepared in the establishments hereinbefore described for the purposes of commerce to be made during the nighttime as well as during the daytime when the slaughtering of said cattle, sheep, swine, goats, horses, mules, and other equines, or the preparation of said food products is conducted during the nighttime.

(Mar. 4, 1907, ch. 2907, title I, § 9, formerly 7th par., 34 Stat. 1262, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 3, 12(a), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 77 of this title.

AMENDMENTS

1967—Pub. L. 90-201, §§ 3, 12(a), deleted "interstate or foreign" preceding "commerce" and "of Agriculture" following "Secretary" and included horses, mules, and other equines in the list of animals, respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 610. Prohibited acts

No person, firm, or corporation shall, with respect to any cattle, sheep, swine, goats, horses, mules, or other equines, or any carcasses, parts of carcasses, meat or meat food products of any such animals—

(a) Slaughtering animals or preparation of articles capable of use as human food

Slaughter any such animals or prepare any such articles which are capable of use as human food at any establishment preparing any such articles for commerce, except in compliance with the requirements of this chapter;

(b) Sales, transportation, and other transactions

Sell, transport, offer for sale or transportation, or receive for transportation, in commerce, (1) any such articles which (A) are capable of use as human food and (B) are adulterated or misbranded at the time of such sale, transportation, offer for sale or transportation, or receipt for transportation; or (2) any articles required to be inspected under this subchapter unless they have been so inspected and passed;

(c) Adulteration or misbranding

Do, with respect to any such articles which are capable of use as human food, any act while they are being transported in commerce or held for sale after such transportation, which is intended to cause or has the effect of causing such articles to be adulterated or misbranded.

(Mar. 4, 1907, ch. 2907, title I, § 10, formerly 8th par., 34 Stat. 1262, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 7, 81 Stat. 584, 589.)

CODIFICATION

Section was formerly classified to section 78 of this title.

AMENDMENTS

1967—Pub. L. 90-201, § 7, included the list of animals and prohibited, except in compliance with requirements of this chapter, slaughtering animals or preparation of articles capable of use as human food, sales, transportation, and other transactions, and acts of adulteration or misbranding, incorporating in par. (b)(2) existing prohibition on distributions in interstate or foreign commerce of noninspected articles.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that pars. (b)(1) and (c) of this section effective upon expiration of sixty days after Dec. 15, 1967, see section 20(a) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 611. Devices, marks, labels, and certificates; simulations

(a) Devices to be made under authorization of Secretary

No brand manufacturer, printer, or other person, firm, or corporation shall cast, print, lithograph, or otherwise make any device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, or any form of official certificate or simulation thereof, except as authorized by the Secretary.

(b) Other misconduct

No person, firm, or corporation shall—

(1) forge any official device, mark, or certificate;

(2) without authorization from the Secretary use any official device, mark, or certificate, or simulation thereof, or alter, detach, deface, or destroy any official device, mark, or certificate;

(3) contrary to the regulations prescribed by the Secretary, fail to use, or to detach, deface, or destroy any official device, mark, or certificate;

(4) knowingly possess, without promptly notifying the Secretary or his representative, any official device or any counterfeit, simulated, forged, or improperly altered official certificate or any device or label or any carcass of any animal, or part or product thereof, bearing any counterfeit, simulated, forged, or improperly altered official mark;

(5) knowingly make any false statement in any shipper's certificate or other nonofficial or official certificate provided for in the regulations prescribed by the Secretary; or

(6) knowingly represent that any article has been inspected and passed, or exempted,

under this chapter when, in fact, it has, respectively, not been so inspected and passed, or exempted.

(Mar. 4, 1907, ch. 2907, title I, § 11, formerly 9th par., 34 Stat. 1263, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 8, 81 Stat. 584, 589.)

CODIFICATION

Section was formerly classified to section 79 of this title.

AMENDMENTS

1967—Pub. L. 90-201, § 8, clarified application to brand manufacturers and printers of existing prohibition against counterfeiting official marks, labels or certificates, the provisions with respect to forgery, unauthorized use or failure to use official marks, or similar items, and similar offenses, and existing prohibitions with respect to false statements in official or nonofficial certificates, and added restriction upon possession of official devices, or devices, labels, meat, or other articles bearing counterfeit official marks, counterfeit official certificates, or similar items, and prohibition against false representations.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 612. Inspection of animals for export

The Secretary shall cause to be made a careful inspection of all cattle, sheep, swine, goats, horses, mules, and other equines intended and offered for export to foreign countries at such times and places, and in such manner as he may deem proper, to ascertain whether such cattle, sheep, swine, goats, horses, mules, and other equines are free from disease.

(Mar. 4, 1907, ch. 2907, title I, § 12, formerly 10th par., 34 Stat. 1263, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 3(b), 12(a), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 80 of this title.

AMENDMENTS

1967—Pub. L. 90-201, §§ 3(b), 12(a), deleted "of Agriculture" following "Secretary" and included horses, mules, and other equines in the list of animals, respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 613 of this title; title 16 section 1540.

§ 613. Inspectors of animals for export; certificates of condition

For the purpose of section 612 of this title the Secretary may appoint inspectors who shall be authorized to give an official certificate clearly stating the condition in which such cattle, sheep, swine, goats, horses, mules, and other equines are found.

(Mar. 4, 1907, ch. 2907, title I, § 13, formerly 11th par., 34 Stat. 1263, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 3(b), 12(a), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 81 of this title.

AMENDMENTS

1967—Pub. L. 90-201, §§ 3(b), 12(a), deleted "of Agriculture" following "Secretary", and included horses, mules, and other equines in the list of animals.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§ 614. Clearance prohibited to vessel carrying animals for export without inspector's certificate

No clearance shall be given to any vessel having on board cattle, sheep, swine, goats, horses, mules, or other equines for export to a foreign country until the owner or shipper of such cattle, sheep, swine, goats, horses, mules, or other equines has a certificate from the inspector authorized to be appointed, stating that the said cattle, sheep, swine, goats, horses, mules, or other equines are sound and healthy, or unless the Secretary shall have waived the requirement of such certificate for export to the particular country to which such cattle, sheep, swine, goats, horses, mules, or other equines are to be exported.

(Mar. 4, 1907, ch. 2907, title I, § 14, formerly 12th par., 34 Stat. 1263, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 3(b), 12(a), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 82 of this title.

AMENDMENTS

1967—Pub. L. 90-201, §§ 3(b), 12(a), deleted "of Agriculture" following "Secretary" and included horses, mules, or other equines in the list of animals, respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 16 section 1540.

§ 615. Inspection of carcasses, meat of which is intended for export

The Secretary shall also cause to be made a careful inspection of the carcasses and parts thereof of all cattle, sheep, swine, goats, horses, mules, and other equines, the meat of which, fresh, salted, canned, corned, packed, cured, or otherwise prepared, is intended and offered for export to any foreign country, at such times and places and in such manner as he may deem proper.

(Mar. 4, 1907, ch. 2907, title I, § 15, formerly 13th par., 34 Stat. 1263, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 3(b), 12(a), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 83 of this title.

AMENDMENTS

1967—Pub. L. 90-201, §§ 3(b), 12(a), deleted "of Agriculture" following "Secretary" and included horses, mules, and other equines in the list of animals, respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 616 of this title.

§ 616. Inspectors of carcasses, etc., meat of which is intended for export; certificates of condition

For the purpose of section 615 of this title the Secretary may appoint inspectors who shall be authorized to give an official certificate stating the condition in which said cattle, sheep, swine, goats, horses, mules, or other equines, and the meat thereof, are found.

(Mar. 4, 1907, ch. 2907, title I, § 16, formerly 14th par., 34 Stat. 1263, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 3(b), 12(a), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 84 of this title.

AMENDMENTS

1967—Pub. L. 90-201, §§ 3(b), 12(a), deleted "of Agriculture" following "Secretary", and included horses, mules, or other equines in the list of animals.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 617. Clearance prohibited to vessel carrying meat for export without inspector's certificate

No clearance shall be given to any vessel having on board any fresh, salted, canned, corned, or packed beef, mutton, pork, goat or equine meat for export to and sale in a foreign country from any port in the United States, until the owner or shipper thereof shall obtain from an inspector appointed under the provisions of this chapter a certificate that the said cattle, sheep, swine, goats, horses, mules, and other equines were sound and healthy at the time of inspection, and that their meat is sound and wholesome, unless the Secretary shall have waived the requirements of such certificate for the country to which said cattle, sheep, swine, goats, horses, mules, and other equines or meats are to be exported.

(Mar. 4, 1907, ch. 2907, title I, § 17, formerly 15th par., 34 Stat. 1263, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 3(b), 12(a), (g), 81 Stat. 584, 588, 592.)

CODIFICATION

Section was formerly classified to section 85 of this title.

AMENDMENTS

1967—Pub. L. 90-201, §§ 3(b), 12(a), (g), deleted "of Agriculture" following "Secretary", included horses, mules, and other equines in the list of animals, and substituted "goat or equine meat" for "or goat meat, being the meat of animals killed after March 4, 1907, or except as hereinbefore provided", respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 618. Delivery of inspectors' certificates, and of copies

The inspectors provided for under this subchapter shall be authorized to give official certificates of the condition of the cattle, sheep, swine, goats, horses, mules, and other equines, their carcasses and products as described in this subchapter; and one copy of every certificate granted under the provisions of this chapter shall be filed in the Department of Agriculture, another copy shall be delivered to the owner or shipper, and when the cattle, sheep, swine, goats, horses, mules, and other equines, or their carcasses and products are sent abroad, a third copy shall be delivered to the chief officer of the vessel on which the shipment shall be made.

(Mar. 4, 1907, ch. 2907, title I, § 18, formerly 16th par., 34 Stat. 1263, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 12(a), (h), 81 Stat. 854, 892.)

CODIFICATION

"Provided for under this subchapter", and "described in this subchapter" in original read "provided for herein" and "herein described", respectively.

Section was formerly classified to section 86 of this title.

AMENDMENTS

1967—Pub. L. 90-201, § 12(a), (h), included horses, mules, and other equines in the list of animals and deleted "sound and wholesome" preceding "conditions", respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 619. Marking, labeling, or other identification of kinds of animals of articles' derivation; separate establishments for preparation and slaughtering activities

No person, firm, or corporation shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any carcasses of horses, mules, or other equines or parts of such carcasses, or the meat or meat food products thereof, unless they are plainly and conspicuously marked or labeled or otherwise identified as required by regulations prescribed by the Secretary to show the kinds of animals from which they were derived. When required by the Secretary, with respect to establishments at which inspection is maintained under this subchapter, such animals and their carcasses, parts thereof, meat and meat food products shall be prepared in establishment separate from those in which cattle, sheep, swine, or goats are slaughtered or their carcasses, parts thereof, meat or meat food products are prepared.

(Mar. 4, 1907, ch. 2907, title I, § 19, formerly 17th par., 34 Stat. 1264, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 9, 81 Stat. 584, 590.)

CODIFICATION

Section was formerly classified to section 87 of this title.

AMENDMENTS

1967—Pub. L. 90-201, § 9, substituted provisions for marking, labeling, or other identification of kinds of animals whence the articles are derived and for separate establishments for preparation and slaughtering activities for prohibition against transportation or sale of meat or meat food products without complying with inspection provisions, now incorporated in section 610(b) of this title.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration, of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 620. Imports

(a) Adulteration or misbranding prohibition; compliance with inspection, building construction standards, and other provisions; treatment as domestic articles subject to this chapter and food, drug, and cosmetic provisions; marking and labeling; personal consumption exemption

No carcasses, parts of carcasses, meat or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines which are capable of use as human food, shall be imported into the United States if such articles are adulterated or misbranded and unless they comply with all the inspection, building, construction standards, and all other provisions of this chapter and regulations issued thereunder applicable to such articles in commerce within the United States. All such imported articles shall, upon entry into the United States, be deemed and treated as domestic articles subject to the other provisions of this chapter and the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]: *Provided*, That they shall be marked and labeled as required by such regulations for imported articles: *Provided further*, That nothing in this section shall apply to any individual who purchases meat or meat products outside the United States for his own consumption except that the total amount of such meat or meat products shall not exceed fifty pounds.

(b) Terms and conditions for destruction

The Secretary may prescribe the terms and conditions for the destruction of all such articles which are imported contrary to this section, unless (1) they are exported by the consignee within the time fixed therefor by the Secretary, or (2) in the case of articles which are not in compliance with the chapter solely because of misbranding, such articles are brought into compliance with the chapter under supervision of authorized representatives of the Secretary.

(c) Payment of storage, cartage, and labor charges by owner or consignee; liens

All charges for storage, cartage, and labor with respect to any article which is imported contrary to this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against such article and any other article thereafter imported under this chapter by or for such owner or consignee.

(d) Prohibition

The knowing importation of any article contrary to this section is prohibited.

(e) Reports to Congress

Not later than March 1 of each year the Secretary shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a comprehensive and detailed written report with respect to the administration of this section during the immediately preceding calendar year. Such report shall include, but shall not be limited to—

(1) a certification by the Secretary that foreign plants exporting carcasses or meat or meat products referred to in subsection (a) of this section have complied with requirements at least equal to all the inspection, building

construction standards, and all other provisions of this chapter and regulations issued thereunder;

(2) the names and locations of plants authorized or permitted to have imported into the United States therefrom carcasses or meat or meat products referred to in subsection (a) of this section;

(3) the number of inspectors employed by the Department of Agriculture in the calendar year concerned who were assigned to inspect plants referred to in paragraph (e)(2) hereof and the frequency with which each such plant was inspected by such inspectors;

(4) the number of inspectors licensed by each country from which any imports subject to the provisions of this section were imported who were assigned, during the calendar year concerned, to inspect such imports and the facilities in which such imports were handled and the frequency and effectiveness of such inspections; and

(5) the total volume of carcasses or meat or meat products referred to in subsection (a) of this section which was imported into the United States during the calendar year concerned from each country, including a separate itemization of the volume of each major category of such imports from each country during such year, and a detailed report of rejections of plants and products because of failure to meet appropriate standards prescribed by this chapter.

(Mar. 4, 1907, ch. 2907, title I, § 20, formerly 18th par., 34 Stat. 1264, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 10, 81 Stat. 584, 590; S. Res. 4, Feb. 4, 1977.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this act to the Code, see section 301 of this title and Tables volume.

CODIFICATION

Section was formerly classified to section 88 of this title.

AMENDMENTS

1967—Pub. L. 90-201, § 10, substituted imported articles provisions for penalty provisions deeming offenses as misdemeanors and punishable by fine of $10,000 or imprisonment for two years or both, now covered in section 676(a) of this title.

CHANGE OF NAME

The Committee on Agriculture and Forestry of the Senate was abolished and replaced by the Committee on Agriculture, Nutrition, and Forestry of the Senate, effective Feb. 11, 1977. See Rule XXV of the Standing Rules of the Senate, as amended by Senate Resolution 4 (popularly cited as the "Committee System Reorganization Amendments of 1977"), approved Feb. 4, 1977.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective upon expiration of sixty days after Dec. 15, 1967, see section 20(a) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

CROSS REFERENCES

Federal Food, Drug, and Cosmetic Act defined, see section 601 of this title.

§ 621. Inspectors to make examinations provided for; appointment; duties; regulations

The Secretary shall appoint from time to time inspectors to make examination and inspection of all cattle, sheep, swine, goats, horses, mules, and other equines, inspection of which is hereby provided for and of all carcasses and parts thereof, and of all meats and meat food products thereof, and of the sanitary conditions of all establishments in which such meat and meat food products hereinbefore described are prepared; and said inspectors shall refuse to stamp, mark, tag, or label any carcass or any part thereof, or meat food product therefrom, prepared in any establishment hereinbefore mentioned, until the same shall have actually been inspected and found to be not adulterated; and shall perform such other duties as are provided by this chapter and by the rules and regulations to be prescribed by said Secretary; and said Secretary shall, from time to time, make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter, and all inspections and examinations made under this chapter, shall be such and made in such manner as described in the rules and regulations prescribed by said Secretary not inconsistent with provisions of this chapter.

(Mar. 4, 1907, ch. 2907, title I, § 21, formerly 19th par., 34 Stat. 1264, renumbered and amended Dec. 15, 1967, Pub. L. 90-201, §§ 1, 3(b), 12(a), (i), 81 Stat. 584, 588, 592, 593.)

CODIFICATION

Section was formerly classified to section 89 of this title.

AMENDMENTS

1967—Pub. L. 90-201, §§ 3(b), 12(a), (i), deleted "of Agriculture" following "Secretary" in four instances, included horses, mules, and other equines in the list of animals, and substituted "not adulterated" for "sound, healthful, wholesome, and fit for human food, and to contain no dyes, chemicals, preservatives, or ingredients which render such meat food product unsound, unhealthful, unwholesome, or unfit for human food; and to have been prepared under proper sanitary conditions, hereinbefore provided for", respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiraton of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 622. Bribery of or gifts to inspectors or other officers and acceptance of gifts

Any person, firm, or corporation, or any agent or employee of any person, firm, or corporation, who shall give, pay, or offer, directly or indirectly, to any inspector, deputy inspector, chief inspector, or any other officer or employee of the United States authorized to perform any of the duties prescribed by this chapter or by the rules and regulations of the Secretary any money or other thing of value, with intent to influence said inspector, deputy inspector, chief inspector, or other officer or employee of the United States in the discharge of

any duty provided for in this chapter, shall be deemed guilty of a felony, and, upon conviction thereof, shall be punished by a fine not less than $5,000 nor more than $10,000 and by imprisonment not less than one year nor more than three years; and any inspector, deputy inspector, chief inspector, or other officer or employee of the United States authorized to perform any of the duties prescribed by this chapter who shall accept any money, gift, or other thing of value from any person, firm, or corporation, or officers, agents, or employees thereof, given with intent to influence his official action, or who shall receive or accept from any person, firm, or corporation engaged in commerce any gift, money, or other thing of value, given with any purpose or intent whatsoever, shall be deemed guilty of a felony and shall, upon conviction thereof, be summarily discharged from office and shall be punished by a fine not less than $1,000 nor more than $10,000 and by imprisonment not less than one year nor more than three years.

(Mar. 4, 1907, ch. 2907, title I, § 22, formerly 20th par., 34 Stat. 1264, renumbered and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 3, 81 Stat. 584, 588.)

CODIFICATION

Section was formerly classified to section 90 of this title.

AMENDMENTS

1967—Pub. L. 90–201, § 3, deleted "interstate or foreign" preceding "commerce" and "of Agriculture" following "Secretary", respectively.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90–201 effective Dec. 15, 1967, except that with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof, amendment effective upon expiration of sixty days after Dec. 15, 1967, see section 20(b) of Pub. L. 90–201, set out as an Effective Date note under section 601 of this title.

§ 623. Exemptions from inspection requirements

(a) Personal slaughtering and custom slaughtering for personal, household, guest, and employee uses

The provisions of this subchapter requiring inspection of the slaughter of animals and the preparation of the carcasses, parts thereof, meat and meat food products at establishments conducting such operations for commerce shall not apply to the slaughtering by any person of animals of his own raising, and the preparation by him and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such animals exclusively for use by him and members of his household and his nonpaying guests and employees; nor to the custom slaughter by any person, firm, or corporation of cattle, sheep, swine or goats delivered by the owner thereof for such slaughter, and the preparation by such slaughterer and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such animals, exclusively for use, in the household of such owner, by him and members of his household and his nonpaying guests and employees; nor to the custom preparation by any person, firm, or corporation of carcasses, parts thereof, meat or meat food products, derived from the slaughter by any person of cattle, sheep, swine, or goats of his own raising, or from game animals, delivered by the owner thereof for such custom preparation, and transportation in commerce of such custom prepared articles, exclusively for use in the household of such owner, by him and members of his household and his nonpaying guests and employees: *Provided*, That in cases where such person, firm, or corporation engages in such custom operations at an establishment at which inspection under this subchapter is maintained, the Secretary may exempt from such inspection at such establishment any animals slaughtered or any meat or meat food products otherwise prepared on such custom basis: *Provided further*, That custom operations at any establishment shall be exempt from inspection requirements as provided by this section only if the establishment complies with regulations which the Secretary is hereby authorized to promulgate to assure that any carcasses, parts thereof, meat or meat food products wherever handled on a custom basis, or any containers or packages containing such articles, are separated at all times from carcasses, parts thereof, meat or meat food products prepared for sale, and that all such articles prepared on a custom basis, or any containers or packages containing such articles, are plainly marked "Not for Sale" immediately after being prepared and kept so identified until delivered to the owner and that the establishment conducting the custom operation is maintained and operated in a sanitary manner.

(b) Territorial exemption; refusal, withdrawal, or modification

The Secretary may, under such sanitary conditions as he may by regulations prescribe, exempt from the inspection requirements of this subchapter the slaughter of animals, and the preparation of carcasses, parts thereof, meat and meat food products, by any person, firm, or corporation in any Territory not organized with a legislative body solely for distribution within such Territory when the Secretary determines that it is impracticable to provide such inspection within the limits of funds appropriated for administration of this chapter and that such exemption will otherwise facilitate enforcement of this chapter. The Secretary may refuse, withdraw, or modify any exemption under this subsection in his discretion whenever he determines such action is necessary to effectuate the purposes of this chapter.

(c) Adulteration and misbranding provisions applicable to inspection-free articles

The adulteration and misbranding provisions of this subchapter, other than the requirement of the inspection legend, shall apply to articles which are exempted from inspection or not required to be inspected under this section.

(Mar. 4, 1907, ch. 2907, title I, § 23, formerly 21st, 22nd pars., 34 Stat. 1265; June 29, 1938, ch. 810, 52 Stat. 1235; renumbered and amended Dec. 15, 1967, Pub. L. 90–201, §§ 1, 11, 81 Stat. 584, 591; July 18, 1970, Pub. L. 91–342, 84 Stat. 438.)

CODIFICATION

Section was formerly classified to section 91 of this title.

AMENDMENTS

1970—Subsec. (a). Pub. L. 91-342 changed the proviso so as to permit custom slaughterers to conduct a separate inspected meat business, continued the exemption for owners to slaughter and process their own animals for their own use, authorized the Secretary to exempt custom slaughtering and processing performed by an inspected establishment, and required that custom slaughtered articles be clearly marked "not for sale".

1967—Pub. L. 90-201, § 11, substituted provisions for personal, custom, and territorial slaughtering exemptions and for application of adulteration and misbranding provisions to inspection-free articles for farmer definition and retail butcher and retail dealer exemption provisions.

1938—Act June 29, 1948, amended section generally.

EFFECTIVE DATE OF 1967 AMENDMENT

Amendment by Pub. L. 90-201 effective upon expiration of sixty days after Dec. 15, 1967, see section 20(c) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 624. Storage and handling regulations; violations; exemption of establishments subject to non-Federal jurisdiction

The Secretary may by regulations prescribe conditions under which carcasses, parts of carcasses, meat, and meat food products of cattle, sheep, swine, goats, horses, mules, or other equines, capable of use as human food, shall be stored or otherwise handled by any person, firm, or corporation engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, or importing, such articles, whenever the Secretary deems such action necessary to assure that such articles will not be adulterated or misbranded when delivered to the consumer. Violation of any such regulation is prohibited. However, such regulations shall not apply to the storage or handling of such articles at any retail store or other establishment in any State or organized Territory that would be subject to this section only because of purchases in commerce, if the storage and handling of such articles at such establishment is regulated under the laws of the State or Territory in which such establishment is located, in a manner which the Secretary, after consultation with the appropriate advisory committee provided for in section 661 of this title, determines is adequate to effectuate the purposes of this section.

(Mar. 4, 1907, ch. 2907, title I, § 24, as added Dec. 15, 1967, Pub. L. 90-201, § 13, 81 Stat. 593.)

SUBCHAPTER II—MEAT PROCESSORS AND RELATED INDUSTRIES

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in sections 607, 661, 672, 673 of this title.

§ 641. Prohibition of subchapter I inspection of articles not intended for use as human food; denaturation or other identification prior to distribution in commerce; inedible articles

Inspection shall not be provided under subchapter I of this chapter at any establishment for the slaughter of cattle, sheep, swine, goats, horses, mules, or other equines, or the preparation of any carcasses or parts or products of such animals, which are not intended for use as human food, but such articles shall, prior to their offer for sale or transportation in commerce, unless naturally inedible by humans, be denatured or otherwise identified as prescribed by regulations of the Secretary to deter their use for human food. No person, firm, or corporation shall buy, sell, transport, or offer for sale or transportation, or receive for transportation, in commerce, or import, any carcasses, parts thereof, meat or meat food products of any such animals, which are not intended for use as human food unless they are denatured or otherwise identified as required by the regulations of the Secretary or are naturally inedible by humans.

(Mar. 4, 1907, ch. 2907, title II, § 201, as added Dec. 15, 1967, Pub. L. 90-201, § 14, 81 Stat. 593.)

EFFECTIVE DATE

Section effective Dec. 15, 1967, see section 20 of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 642. Recordkeeping requirements

(a) Classes of persons bound; scope of disclosure; access to places of business; examination of records, facilities, and inventories; copies; samples

The following classes of persons, firms, and corporations shall keep such records as will fully and correctly disclose all transactions involved in their businesses; and all persons, firms, and corporations subject to such requirements shall, at all reasonable times upon notice by a duly authorized representative of the Secretary, afford such representative access to their places of business and opportunity to examine the facilities, inventory, and records thereof, to copy all such records, and to take reasonable samples of their inventory upon payment of the fair market value therefor—

(1) Any persons, firms, or corporations that engage, for commerce, in the business of slaughtering any cattle, sheep, swine, goats, horses, mules, or other equines, or preparing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any such animals, for use as human food or animal food;

(2) Any persons, firms, or corporations that engage in the business of buying or selling (as meat brokers, wholesalers or otherwise), or transporting in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any such animals;

(3) Any persons, firms, or corporations that engage in business, in or for commerce, as renderers, or engage in the business of buying, selling, or transporting, in commerce, or importing, any dead, dying, disabled, or diseased cattle, sheep, swine, goats, horses, mules, or other equines, or parts of the carcasses of any such animals that died otherwise than by slaughter.

(b) Period of maintenance

Any record required to be maintained by this section shall be maintained for such period of

time as the Secretary may by regulations prescribe.

(Mar. 4, 1907, ch. 2907, title II, § 202, as added Dec. 15, 1967, Pub. L. 90-201, § 14, 81 Stat. 593.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 645, 678 of this title.

§ 643. Registration of business, name of person, and trade names

No person, firm, or corporation shall engage in business, in or for commerce, as a meat broker, renderer, or animal food manufacturer, or engage in business in commerce as a wholesaler of any carcasses, or parts or products of the carcasses, of any cattle, sheep, swine, goats, horses, mules, or other equines, whether intended for human food or other purposes, or engage in business as a public warehouseman storing any such articles in or for commerce, or engage in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased animals of the specified kinds, or parts of the carcasses of any such animals that died otherwise than by slaughter, unless, when required by regulations of the Secretary, he has registered with the Secretary his name, and the address of each place of business at which, and all trade names under which, he conducts such business.

(Mar. 4, 1907, ch. 2907, title II, § 203, as added Dec. 15, 1967, Pub. L. 90-201, § 14, 81 Stat. 594.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 645 of this title.

§ 644. Regulation of transactions, transportation, or importation of 4-D animals to prevent use as human food

No person, firm, or corporation engaged in the business of buying, selling, or transporting in commerce, or importing, dead, dying, disabled, or diseased animals, or any parts of the carcasses of any animals that died otherwise than by slaughter, shall buy, sell, transport, offer for sale or transportation, or receive for transportation, in commerce, or import, any dead, dying, disabled, or diseased cattle, sheep, swine, goats, horses, mules or other equines, or parts of the carcasses of any such animals that died otherwise than by slaughter, unless such transaction, transportation or importation is made in accordance with such regulations as the Secretary may prescribe to assure that such animals, or the unwholesome parts or products thereof, will be prevented from being used for human food purposes.

(Mar. 4, 1907, ch. 2907, title II, § 204, as added Dec. 15, 1967, Pub. L. 90-201, § 14, 81 Stat. 594.)

EFFECTIVE DATE

Section effective upon expiration of sixty days after Dec. 15, 1967, see section 20(d) of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 645 of this title.

§ 645. Federal provisions applicable to State or Territorial business transactions of a local nature and not subject to local authority

The authority conferred on the Secretary by section 642, 643, or 644 of this title with respect to persons, firms, and corporations engaged in the specified kinds of business in or for commerce may be exercised with respect to persons, firms, or corporations engaged, in any State or organized Territory, in such kinds of business but not in or for commerce, whenever the Secretary determines, after consultation with an appropriate advisory committee provided for in section 661 of this title, that the State or territory does not have at least equal authority under its laws or such authority is not exercised in a manner to effectuate the purposes of this chapter including the State providing for the Secretary or his representative being afforded access to such places of business and the facilities, inventories, and records thereof, and the taking of reasonable samples, where he determines necessary in carrying out his responsibilities under this chapter; and in such case the provisions of section 642, 643, or 644 of this title, respectively, shall apply to such persons, firms, and corporations to the same extent and in the same manner as if they were engaged in such business in or for commerce and the transactions involved were in commerce.

(Mar. 4, 1907, ch. 2907, title II, § 205, as added Dec. 15, 1967, Pub. L. 90-201, § 14, 81 Stat. 594.)

SUBCHAPTER III—FEDERAL AND STATE COOPERATION

§ 661. Federal and State cooperation

(a) Congressional statement of policy

It is the policy of the Congress to protect the consuming public from meat and meat food products that are adulterated or misbranded and to assist in efforts by State and other Government agencies to accomplish this objective. In furtherance of this policy—

(1) Development and administration of State meat inspection program equal to subchapter I ante and post mortem inspection, reinspection, and sanitation requirements

The Secretary is authorized, whenever he determines that it would effectuate the purposes of this chapter, to cooperate with the appropriate State agency in developing and administering a State meat inspection program in any State which has enacted a State meat inspection law that imposes mandatory ante mortem and post mortem inspection, reinspection and sanitation requirements that are at least equal to those under subchapter I of this chapter, with respect to all or certain classes of persons engaged in the State in slaughtering cattle, sheep, swine, goats, or equines, or preparing the carcasses, parts thereof, meat or meat food products, of any such animals for use as human food solely for distribution within such State.

(2) Development and administration of State program with authorities equal to subchapter II authorities; cooperation with Federal agencies

The Secretary is further authorized, whenever he determines that it would effectuate the purposes of this chapter, to cooperate

with appropriate State agencies in developing and administering State programs under State laws containing authorities at least equal to those provided in subchapter II of this chapter; and to cooperate with other agencies of the United States in carrying out any provisions of this chapter.

(3) Scope of cooperation: advisory assistance, technical and laboratory assistance and training, and financial and other aid; limitation on amount; equitable allocation of Federal funds; adequacy of State program to obtain Federal cooperation and payments

Cooperation with State agencies under this section may include furnishing to the appropriate State agency (i) advisory assistance in planning and otherwise developing an adequate State program under the State law; and (ii) technical and laboratory assistance and training (including necessary curricular and instructional materials and equipment), and financial and other aid for administration of such a program. The amount to be contributed to any State by the Secretary under this section from Federal funds for any year shall not exceed 50 per centum of the estimated total cost of the cooperative program; and the Federal funds shall be allocated among the States desiring to cooperate on an equitable basis. Such cooperation and payment shall be contingent at all times upon the administration of the State program in a manner which the Secretary, in consultation with the appropriate advisory committee appointed under paragraph (4), deems adequate to effectuate the purposes of this section.

(4) Advisory committees

The Secretary may appoint advisory committees consisting of such representatives of appropriate State agencies as the Secretary and the State agencies may designate to consult with him concerning State and Federal programs with respect to meat inspection and other matters within the scope of this chapter, including evaluating State programs for purposes of this chapter and obtaining better coordination and more uniformity among the State programs and between the Federal and State programs and adequate protection of consumers.

(b) Single State agency; subordinate governmental unit as part of State agency

The appropriate State agency with which the Secretary may cooperate under this chapter shall be a single agency in the State which is primarily responsible for the coordination of the State programs having objectives similar to those under this chapter. When the State program includes performance of certain functions by a municipality or other subordinate governmental unit, such unit shall be deemed to be a part of the State agency for purposes of this section.

(c) State meat inspection requirements

(1) Notice to Governor of nondevelopment or nonenforcement; designation of State as subject to subchapters I and IV; delay and revocation of designation; publication in Federal Register; notice of production of adulterated meat or meat food products; designation of State

If the Secretary has reason to believe, by thirty days prior to the expiration of two years after enactment of the Wholesome Meat Act, that a State has failed to develop or is not enforcing, with respect to all establishments within its jurisdiction (except those that would be exempted from Federal inspection under subparagraph (2)) at which cattle, sheep, swine, goats, or equines are slaughtered, or their carcasses, or parts or products thereof, are prepared for use as human food, solely for distribution within such State, and the products of such establishments, requirements at least equal to those imposed under subchapter I and IV of this chapter, he shall promptly notify the Governor of the State of this fact. If the Secretary determines, after consultation with the Governor of the State, or representative selected by him, that such requirements have not been developed and activated, he shall promptly after the expiration of such two-year period designate such State as one in which the provisions of subchapters I and IV of this chapter shall apply to operations and transactions wholly within such State: *Provided*, That if the Secretary has reason to believe that the State will activate such requirements within one additional year, he may delay such designation for said period, and not designate the State, if he determines at the end of the year that the State then has such requirements in effective operation. The Secretary shall publish any such designation in the Federal Register and, upon the expiration of thirty days after such publication, the provisions of subchapters I and IV shall apply to operations and transactions and to persons, firms, and corporations engaged therein in the State to the same extent and in the same manner as if such operations and transactions were conducted in or for commerce. Thereafter, upon request of the Governor, the Secretary shall revoke such designation if the Secretary determines that such State has developed and will enforce requirements at least equal to those imposed under subchapter I and subchapter IV of this chapter: *And provided further*, That, notwithstanding any other provision of this section, if the Secretary determines that any establishment within a State is producing adulterated meat or meat food products for distribution within such State which would clearly endanger the public health he shall notify the Governor of the State and the appropriate Advisory Committee provided by section 661 of this title of such fact for effective action under State or local law. If the State does not take action to prevent such endangering of the public health within a reasonable time after such notice, as determined by the Secretary, in light of the risk to public health, the Secretary may forthwith designate any such establishment as subject to the provisions of subchapters I and IV of this chapter, and thereupon the establishment and operator

thereof shall be subject to such provisions as though engaged in commerce until such time as the Secretary determines that such State has developed and will enforce requirements at least equal to those imposed under subchapter I and subchapter IV of this chapter.

(2) Exemptions of retail stores, restaurants, and similar retail-type establishments

The provisions of this chapter requiring inspection of the slaughter of animals and the preparation of carcasses, parts thereof, meat and meat food products shall not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments if such establishments are subject to such inspection provisions only under this paragraph (c).

(3) Termination of designation of State upon development and enforcement of minimum requirements; redesignation; designation for nonenforcement of minimum requirements: notice and publication in Federal Register

Whenever the Secretary determines that any State designated under this paragraph (c) has developed and will enforce State meat inspection requirements at least equal to those imposed under subchapters I and IV of this chapter with respect to the operations and transactions within such State which are regulated under paragraph (1), he shall terminate the designation of such State under this paragraph (c), but this shall not preclude the subsequent redesignation of the State at any time upon thirty days notice to the Governor and publication in the Federal Register in accordance with this paragraph, and any State may be designated upon such notice and publication at any time after the period specified in this paragraph whether or not the State has theretofore been designated upon the Secretary determining that it is not effectively enforcing requirements at least equal to those imposed under subchapters I and IV of this chapter.

(4) Periodic review; report to Congress

The Secretary shall promptly upon enactment of the Wholesome Meat Act and periodically thereafter, but at least annually, review the requirements, including the enforcement thereof, of the several States not designated under this paragraph (c), with respect to the slaughter, and the preparation, storage, handling and distribution of carcasses, parts thereof, meat and meat food products, of such animals, and inspection of such operations and annually report thereon to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate in the report required under section 691 of this title.

(d) Definition of "State"

As used in this section, the term "State" means any State (including the Commonwealth of Puerto Rico) or organized Territory.

(Mar. 4, 1907, ch. 2907, title III § 301, as added Dec. 15, 1967, Pub. L. 90-201, § 15, 81 Stat. 595, and amended S. Res. 4, Feb. 4, 1977.)

REFERENCES IN TEXT

Enactment of the Wholesome Meat Act, referred to in subsec. (c)(1), (4), means Dec. 15, 1967, the date of enactment of Pub. L. 90-201.

CHANGE OF NAME

The Committee on Agriculture and Forestry of the Senate was abolished and replaced by the Committee on Agriculture, Nutrition, and Forestry of the Senate, effective Feb. 11, 1977. See Rule XXV of the Standing Rules of the Senate, as amended by Senate Resolution 4 (popularly cited as the "Committee System Reorganization Amendments of 1977"), approved Feb. 4, 1977.

EFFECTIVE DATE

Section effective Dec. 15, 1967, see section 20 of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of two year period following Jan. 5, 1973, and advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of two year period beginning on the date of their establishment, unless in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such two year period, or in the case of a committee established by Congress, its duration is otherwise provided by law, see section 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 607, 624, 645 of this title.

SUBCHAPTER IV—AUXILIARY PROVISIONS

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in section 661 of this title.

§ 671. Inspection services; refusal or withdrawal; hearing; business unfitness based upon certain convictions; other provisions for withdrawal of services unaffected; responsible connection with business; finality of Secretary's actions; judicial review; record

The Secretary may (for such period, or indefinitely, as he deems necessary to effectuate the purposes of this chapter) refuse to provide, or withdraw, inspection service under subchapter I of this chapter with respect to any establishment if he determines, after opportunity for a hearing is accorded to the applicant for, or recipient of, such service, that such applicant or recipient is unfit to engage in any business requiring inspection under subchapter I because the applicant or recipient, or anyone responsibly connected with the applicant or recipient, has been convicted, in any Federal or State court, of (1) any felony, or (2) more than one violation of any law, other than a felony, based upon the acquiring, handling, or distributing of unwholesome, mislabeled, or deceptively packaged food or upon fraud in connection with transactions in food. This section shall not affect in any way other provisions of this chapter for withdrawal of inspection services under subchapter I from establishments failing to maintain sanitary conditions or to destroy con-

demned carcasses, parts, meat or meat food products.

For the purpose of this section a person shall be deemed to be responsibly connected with the business if he was a partner, officer, director, holder, or owner of 10 per centum or more of its voting stock or employee in a managerial or executive capacity.

The determination and order of the Secretary with respect thereto under this section shall be final and conclusive unless the affected applicant for, or recipient of, inspection service files application for judicial review within thirty days after the effective date of such order in the appropriate court as provided in section 674 of this title. Judicial review of any such order shall be upon the record upon which the determination and order are based.

(Mar. 4, 1907, ch. 2907, title IV, § 401, as added Dec. 15, 1967, Pub. L. 90-201, § 16, 81 Stat. 597.)

EFFECTIVE DATE

Section effective Dec. 15, 1967, see section 20 of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

§ 672. Administrative detention; duration; pending judicial proceedings; notification of governmental authorities; release

Whenever any carcass, part of a carcass, meat or meat food product of cattle, sheep, swine, goats, horses, mules, or other equines, or any product exempted from the definition of a meat food product, or any dead, dying, disabled, or diseased cattle, sheep, swine, goat, or equine is found by any authorized representative of the Secretary upon any premises where it is held for purposes of, or during or after distribution in, commerce or otherwise subject to subchapter I or II of this chapter, and there is reason to believe that any such article is adulterated or misbranded and is capable of use as human food, or that it has not been inspected, in violation of the provisons of subchapter I of this chapter or of any other Federal law or the laws of any State or Territory, or the District of Columbia, or that such article or animal has been or is intended to be, distributed in violation of any such provisions, it may be detained by such representative for a period not to exceed twenty days, pending action under section 673 of this title or notification of any Federal, State, or other governmental authorities having jurisdiction over such article or animal, and shall not be moved by any person, firm, or corporation from the place at which it is located when so detained, until released by such representative. All official marks may be required by such representative to be removed from such article or animal before it is released unless it appears to the satisfaction of the Secretary that the article or animal is eligible to retain such marks.

(Mar. 4, 1907, ch. 2907, title IV, § 402, as added Dec. 15, 1967, Pub. L. 90-201, § 16, 81 Stat. 598.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 679 of this title.

§ 673. Seizure and condemnation

(a) Proceedings in rem; libel of information; jurisdiction; disposal by destruction or sale; proceeds into the Treasury; sales restrictions; bond; court costs and fees, storage, and other expenses against claimants; proceedings in admiralty; jury trial; United States as plaintiff

Any carcass, part of a carcass, meat or meat food product of cattle, sheep, swine, goats, horses, mules or other equines, or any dead, dying, disabled, or diseased cattle, sheep, swine, goat, or equine, that is being transported in commerce or otherwise subject to subchapter I or II of this chapter, or is held for sale in the United States after such transportation, and that (1) is or has been prepared, sold, transported, or otherwise distributed or offered or received for distribution in violation of this chapter, or (2) is capable of use as human food and is adulterated or misbranded, or (3) in any other way is in violation of this chapter, shall be liable to be proceeded against and seized and condemned, at any time, on a libel of information in any United States district court or other proper court as provided in section 674 of this title within the jurisdiction of which the article or animal is found. If the article or animal is condemned it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs and fees, and storage and other proper expenses, shall be paid into the Treasury of the United States, but the article or animal shall not be sold contrary to the provisions of this chapter, or the laws of the jurisdiction in which it is sold: *Provided*, That upon the execution and delivery of a good and sufficient bond conditioned that the article or animal shall not be sold or otherwise disposed of contrary to the provisions of this chapter, or the laws of the jurisdiction in which disposal is made, the court may direct that such article or animal be delivered to the owner thereof subject to such supervision by authorized representatives of the Secretary as is necessary to insure compliance with the applicable laws. When a decree of condemnation is entered against the article or animal and it is released under bond, or destroyed, court costs and fees, and storage and other proper expenses shall be awarded against the person, if any, intervening as claimant of the article or animal. The proceedings in such libel cases shall conform, as nearly as may be, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

(b) Condemnation or seizure under other provisions unaffected

The provisions of this section shall in no way derogate from authority for condemnation or seizure conferred by other provisions of this chapter, or other laws.

(Mar. 4, 1907, ch. 2907, title IV, § 403, as added Dec. 15, 1967, Pub. L. 90-201, § 16, 81 Stat. 598.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 672 of this title.

§ 674. Federal court jurisdiction of enforcement and injunction proceedings and other kinds of cases; limitations of section 607(e) of this title

The United States district courts, the District Court of Guam, the District Court of the Virgin Islands, the highest court of American Samoa, and the United States courts of the other Territories, are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this chapter, and shall have jurisdiction in all other kinds of cases arising under this chapter, except as provided in section 607(e) of this title.

(Mar. 4, 1907, ch. 2907, title IV, § 404, as added Dec. 15, 1967, Pub. L. 90-201, § 16, 81 Stat. 599.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 671, 673, 677 of this title.

§ 675. Assaulting, resisting, or impeding certain persons; murder; protection of such persons

Any person who forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any person while engaged in or on account of the performance of his official duties under this chapter shall be fined not more than $5,000 or imprisoned not more than three years, or both. Whoever, in the commission of any such acts, uses a deadly or dangerous weapon, shall be fined not more than $10,000 or imprisoned not more than ten years, or both. Whoever kills any person while engaged in or on account of the performance of his official duties under this chapter shall be punished as provided under sections 1111 and 1114 of title 18.

(Mar. 4, 1907, ch. 2907, title IV, § 405, as added Dec. 15, 1967, Pub. L. 90-201, § 16, 81 Stat. 599.)

§ 676. Violations

(a) Misdemeanors; felonies: intent to defraud and distribution of adulterated articles; good faith

Any person, firm, or corporation who violates any provision of this chapter for which no other criminal penalty is provided by this chapter shall upon conviction be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if such violation involves intent to defraud, or any distribution or attempted distribution of an article that is adulterated (except as defined in section 601(m)(8) of this title), such person, firm, or corporation shall be subject to imprisonment for not more than three years or a fine of not more than $10,000, or both: *Provided*, That no person, firm, or corporation, shall be subject to penalties under this section for receiving for transportation any article or animal in violation of this chapter if such receipt was made in good faith, unless such person, firm, or corporation refuses to furnish on request of a representative of the Secretary the name and address of the person from whom he received such article or animal, and copies of all documents, if any there be, pertaining to the delivery of the article or animal to him.

(b) Minor violations; written warning or criminal and civil proceedings

Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice of warning.

(Mar. 4, 1907, ch. 2907, title IV, § 406, as added Dec. 15, 1967, Pub. L. 90-201, § 16, 81 Stat. 599.)

§ 677. Other Federal laws applicable for administration and enforcement of chapter; location of inquiries; jurisdiction of Federal courts

For the efficient administration and enforcement of this chapter, the provisions (including penalties) of sections 46, 48, 49 and 50 of title 15 (except paragraphs (c) through (h) of section 46 and the last paragraph of section 49), and the provisions of section 409(*l*) of title 47; are made applicable to the jurisdiction, powers, and duties of the Secretary in administering and enforcing the provisions of this chapter and to any person, firm, or corporation with respect to whom such authority is exercised. The Secretary, in person or by such agents as he may designate, may prosecute any inquiry necessary to his duties under this chapter in any part of the United States, and the powers conferred by said sections 49 and 50 of title 15 on the district courts of the United States may be exercised for the purposes of this chapter by any court designated in section 674 of this title.

(Mar. 4, 1907, ch. 2907, title IV, § 407, as added Dec. 15, 1967, Pub. L. 90-201, § 16, 81 Stat. 599.)

REFERENCES IN TEXT

The last paragraph of section 49 of title 15, and the provisions of section 409(*l*) of title 47, referred to in the text, which related to immunity of witnesses, were repealed by sections 211 and 242, respectively, of Pub. L. 91-452, Oct. 15, 1970, title II, 84 Stat. 929, 930. For current provisions relating to immunity of witnesses, see section 6001 et seq. of Title 18, Crimes and Criminal Procedure.

§ 678. Non-Federal jurisdiction of Federally regulated matters; prohibition of additional or different requirements for establishments with inspection services and as to marking, labeling, packaging, and ingredients; recordkeeping and related to requirements; concurrent jurisdiction over distribution for human food purposes of adulterated or misbranded and imported articles; other matters

Requirements within the scope of this chapter with respect to premises, facilities and operations of any establishment at which inspection is provided under subchapter I of this chapter, which are in addition to, or different than those made under this chapter may not be imposed by any State or Territory or the District of Columbia, except that any such jurisdiction may impose recordkeeping and other requirements within the scope of section 642 of this title, if consistent therewith, with respect to any such establishment. Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establish-

ment under inspection in accordance with the requirements under subchapter I of this chapter, but any State or Territory or the District of Columbia may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under said subchapter I, for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles which are not at such an establishment, after their entry into the United States. This chapter shall not preclude any State or Territory or the District of Columbia from making requirement or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

(Mar. 4, 1907, ch. 2907, title IV, § 408, as added Dec. 15, 1967, Pub. L. 90-201, § 16, 81 Stat. 600.)

§ 679. Federal Food, Drug, and Cosmetic Act applications

(a) Authorities under food, drug, and cosmetic provisions unaffected

Notwithstanding any other provisions of law, including section 902(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 392(a)), the provisions of this chapter shall not derogate from any authority conferred by the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] prior to December 15, 1967.

(b) Enforcement proceedings; detainer authority of representatives of Secretary of Health, Education, and Welfare

The detainer authority conferred by section 672 of this title shall apply to any authorized representative of the Secretary of Health, Education, and Welfare for purposes of the enforcement of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] with respect to any carcass, part thereof, meat, or meat food product of cattle, sheep, swine, goats, or equines that is outside any premises at which inspection is being maintained under this chapter, and for such purposes the first reference to the Secretary in section 672 of this title shall be deemed to refer to the Secretary of Health, Education, and Welfare.

(Mar. 4, 1907, ch. 2907, title IV, § 409, as added Dec. 15, 1967, Pub. L. 90-201, § 16, 81 Stat. 600.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables volume.

CROSS REFERENCES

Federal Food, Drug, and Cosmetic Act defined, see section 601 of this title.

§ 680. Authorization of appropriations

There are hereby authorized to be appropriated such sums as may be necessary to carry out the provisions of this chapter.

(Mar. 4, 1907, ch. 2907, title IV, § 410, as added Dec. 15, 1967, Pub. L. 90-201, § 16, 81 Stat. 600.)

SUBCHAPTER V—MISCELLANEOUS PROVISIONS

§ 691. Reports to Congress

The Secretary shall annually report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate with respect to the slaughter of animals subject to this Act, and the preparation, storage, handling and distribution of carcasses, parts thereof, meat and meat food products, of such animals, and inspection of establishments operated in connection therewith, including the operations under and effectiveness of this Act.

(Pub. L. 90-201, § 17, Dec. 15, 1967, 81 Stat. 600; S. Res. 4, Feb. 4, 1977.)

REFERENCES IN TEXT

This Act, referred to in text, means Pub. L. 90-201, Dec. 15, 1967, 81 Stat. 584, known as the Wholesome Meat Act, which enacted sections 601, 602, 624, 641 to 645, 661, 671 to 680, and 691 of this title, amended sections 603 to 623 of this title, repealed section 96 of this title and section 1306(b) of Title 19, Customs Duties, and enacted provisions set out as notes under this section. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables volume.

CODIFICATION

Section was enacted as a part of the Wholesome Meat Act (see References in Text note above) and not as a part of the Federal Meat Inspection Act which is classified to subchapters I to IV of this chapter.

CHANGE OF NAME

The Committee on Agriculture and Forestry of the Senate was abolished and Replaced by the Committee on Agriculture, Nutrition, and Forestry of the Senate, effective Feb. 11, 1977. See Rule XXV of the Standing Rules of the Senate, as amended by Senate Resolution 4 (popularly cited as the "Committee System Reorganization Amendments of 1977"), approved Feb. 4, 1977.

EFFECTIVE DATE

Section effective Dec. 15, 1967, see section 20 of Pub. L. 90-201, set out as an Effective Date note under section 601 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 661 of this title.

§ 692. Inspection extended to reindeer

The provisions of the meat inspection law may be extended to the inspection of reindeer.

(June 30, 1914, ch. 131, 38 Stat. 420.)

REFERENCES IN TEXT

The "meat inspection law", referred to in text, is classified generally to this chapter. At time of enactment, such reference probably meant the Act of Mar. 4, 1907, ch. 2907, 34 Stat. 1260, as amended. That Act (formerly classified to section 71 et seq. of this title), was generally revised by Pub. L. 90-201, Dec. 15, 1967, 81 Stat. 584, and is now classified to this chapter.

CODIFICATION

Section was not enacted as part of the Federal Meat Inspection Act which is classified to subchapters I to IV of this chapter.

Section was formerly classified to section 94 of this title.

§ 693. Inspection of dairy products for export

The act of March 3, 1891, as amended, for the inspection of live cattle and products thereof, shall be deemed to include dairy products intended for exportation to any foreign country, and the Secretary of Agriculture may apply, under rules and regulations to be prescribed by him, the provisions of said act for inspection and certification appropriate for ascertaining the purity and quality of such products, and may cause the same to be so marked, stamped, or labeled as to secure their identity and make known in the markets of foreign countries to which they may be sent from the United States their purity, quality, and grade; and all the provisions of said act relating to live cattle and products thereof for export shall apply to dairy products so inspected and certified.

(May 23, 1908, ch. 192, 35 Stat. 254.)

REFERENCES IN TEXT

The act of March 3, 1891, referred to in text, is act Mar. 3, 1891, ch. 555, 26 Stat. 1089, which was superseded by act Mar. 4, 1907, ch. 2907, 34 Stat. 1260, as amended by act June 29, 1938, ch. 810, 52 Stat. 1235 (formerly classified to section 71 et seq. of this title). Act Mar. 4, 1907, ch. 2907, was generally revised by Pub. L. 90-201, Dec. 15, 1967, 81 Stat. 584, and is now classified to this chapter.

CODIFICATION

Section was not enacted as part of the Federal Meat Inspection Act which is classified to subchapters I to IV of this chapter.

Section was formerly classified to section 94a of this title.

§ 694. Authorization of appropriations

Annual appropriations of the sum of $3,000,000 from the general fund of the Treasury are authorized for the expenses of the inspection of cattle, sheep, swine, and goats and the meat and meat food products thereof which enter into interstate or foreign commerce and for all expenses necessary to carry into effect the provisions of act June 30, 1906, relating to meat inspection, including rent and the employment of labor in Washington and elsewhere, for each year, and in addition there is authorized to be appropriated such other sums as may be necessary in the enforcement of the meat inspection laws.

(June 30, 1906, ch. 3913, 34 Stat. 679; June 26, 1934, ch. 756, § 2, 48 Stat. 1225.)

REFERENCES IN TEXT

Act June 30, 1906, referred to in the text, is act June 30, 1906, ch. 3913, 34 Stat. 679, which made appropriations for the Department of Agriculture for the fiscal year ending June 30, 1907.

CODIFICATION

Act June 26, 1934, repealed provisions which authorized permanent appropriations, and authorized in lieu thereof an annual appropriation from the general fund of the Treasury, and in addition thereto, the appropriation of "such other sums as may be necessary in the enforcement of the meat inspection laws." See section 725a(a), (b) of Title 31, Money and Finance. In the original, the parenthetical "(U.S.C., title 21, secs. 71 to 96, inclusive)" followed the phrase "meat inspection laws". The "meat inspection laws" are now classified generally to this chapter.

Section was not enacted as part of the Federal Meat Inspection Act which is classified to subchapters I to IV of this chapter.

Section was formerly classified to section 95 of this title.

§ 695. Payment of cost of meat-inspection service; exception

The cost of inspection rendered on and after July 1, 1948, under the requirements of laws relating to Federal inspection of meat and meat food products shall be borne by the United States except the cost of overtime pursuant to section 394 of title 7.

(June 5, 1948, ch. 423, 62 Stat. 344.)

CODIFICATION

Section was not enacted as part of the Federal Meat Inspection Act which is classified to subchapters I to IV of this chapter.

Section was formerly classified to section 98 of this title.

CHAPTER 13—DRUG ABUSE PREVENTION AND CONTROL

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CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in title 22 sections 283s, 284k, 285p, 2291.

SUBCHAPTER I—CONTROL AND ENFORCEMENT

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in sections 951, 952, 958, 962, 965 of this title; title 40 section 304m; title 42 sections 242, 281.

PART A—INTRODUCTORY PROVISIONS

§ 801. Congressional findings and declarations

The Congress makes the following findings and declarations:

(1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.

(3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because—

(A) after manufacture, many controlled substances are transported in interstate commerce,

(B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

(C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.

(7) The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective control over international and domestic traffic in controlled substances.

(Pub. L. 91-513, title II, § 101, Oct. 27, 1970, 84 Stat. 1242.)

REFERENCES IN TEXT

"This subchapter", referred to in par. (1), was in the original "this title" which is title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, and is popularly known as the "Controlled Substances Act". For complete classification of title II to the Code, see second paragraph of Short Title note set out below and Tables volume.

EFFECTIVE DATE

Section 704 of Pub. L. 91-513 provided that:

"(a) Except as otherwise provided in this section, this title [see Short Title note under this section] shall become effective on the first day of the seventh calendar month that begins after the day immediately preceding the date of enactment [Oct. 27, 1970].

"(b) Parts A, B, E, and F of this title, [Parts A, B, E, and F of this subchapter], section 702 [set out as a note under section 321 of this title], this section, and sections 705 through 709 [set out as sections 901 to 904 of this title and as a note under this section] shall become effective upon enactment [Oct. 27, 1970].

"(c) Sections 305 (relating to labels and labeling), [section 825 of this title], and 306 (relating to manufacturing quotas) [section 826 of this title] shall become effective on the date specified in subsection (a) of this section, except that the Attorney General may by order published in the Federal Register postpone the effective date of either or both of these sections for such period as he may determine to be necessary for the efficient administration of this title [this subchapter]."

SHORT TITLE OF 1974 AMENDMENT

Section 1 of Pub. L. 93-281 provided: "That this Act [amending sections 802, 823, 824, and 827 of this title] may be cited as the 'Narcotic Addict Treatment Act of 1974'."

SHORT TITLE

Pub. L. 91-513, in the provisions preceding section 1 immediately following the enacting clause, provided: "That this Act [enacting this chapter and sections 257a, 2688*l*-1, 2688n-1, and 3509 of Title 42, The Public Health and Welfare, amending sections 162, 198a, 321, 331, 333, 334, 360, 372, and 381 of this title, sections 1114, 1952, and 4251 of Title 18, Crimes and Criminal Procedure, section 1584 of Title 19, Customs Duties, sections 4901, 4905, 6808, 7012, 7103, 7326, 7607, 7609, 7641, 7651, and 7655 of Title 26, Internal Revenue Code, section 2901 of Title 28, Judiciary and Judicial Procedure, sections 529d, 529e, and 529f of Title 31, Money and Finance, section 304m of Title 40, Public Buildings, Property, and Works, sections 201, 225a, 242, 242a, 246, 257, 258, 259, 260, 261, 261a, 2688k, 2688*l*, 2688m, 2688n, 2688o, 2688r, and 3411 of Title 42, The Public Health and Welfare, section 239a of Title 46, Shipping, and section 787 of Title 49, Transportation, repealing sections 171 to 174, 176 to 185, 188 to 188n, 191 to 193, 197, 198, 199, 360a, and 501 to 517 of this title, sections 1401 to 1407 and 3616 of Title 18, sections 4701 to 4707, 4711 to 4716, 4721 to 4726, 4731 to 4736, 4741 to 4746, 4751 to 4757, 4761, 4762, 4771 to 4776, 7237, 7238, and 7491 of Title 26, sections 529a and 529g of Title 31, and section 1421m of Title 48, Territories and Insular Possessions, and enacting provisions set out as notes under this section and sections 171, 321, 822, 951, and 957 of this title] may be cited as the 'Comprehensive Drug Abuse Prevention and Control Act of 1970'."

Section 100 of title II of Pub. L. 91-513 provided that: "This title [enacting this subchapter, repealing section 360a of this title, amending sections 321, 331, 333, 334, 360, 372, and 381 of this title, sections 1114 and 1952 of Title 18, Crimes and Criminal Procedure, and section 242 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under this section and sections 321 and 822 of this title] may be cited as the 'Controlled Substances Act'."

CONTINUATION OF ORDERS, RULES, AND REGULATIONS

Section 705 of Pub. L. 91-513 provided that: "Any orders, rules, and regulations which have been promulgated under any law affected by this title [this subchapter] and which are in effect on the day preceding enactment of this title [Oct. 27, 1970] shall continue in effect until modified, superseded, or repealed."

COMMISSION ON MARIHUANA AND DRUG ABUSE

Section 601 of Pub. L. 91-513, as amended by Pub. L. 92-13, May 14, 1971, 85 Stat. 37, provided that:

"(a) [Establishment; composition] There is established a commission to be known as the Commission on Marihuana and Drug Abuse (hereafter in this section referred to as the 'Commission'). The Commission shall be composed of—

"(1) two Members of the Senate appointed by the President of the Senate;

"(2) two Members of the House of Representatives appointed by the Speaker of the House of Representatives; and

"(3) nine members appointed by the President of the United States.

At no time shall more than one of the members appointed under paragraph (1), or more than one of the members appointed under paragraph (2), or more than five of the members appointed under paragraph (3) be members of the same political party.

"(b) [Chairman; Vice Chairman; compensation of members; meetings] (1) The President shall designate one of the members of the Commission as Chairman and one as Vice Chairman. Seven members of the Commission shall constitute a quorum, but a lesser number may conduct hearings.

"(2) Members of the Commission who are Members of Congress or full-time officers or employees of the United States shall serve without additional compensation but shall be reimbursed for travel, subsistence, and other necessary expenses incurred in the performance of the duties vested in the Commission. Members of the Commission from private life shall receive $100 per diem while engaged in the actual performance of the duties vested in the Commission, plus reimbursement for travel, subsistence, and other necessary expenses incurred in the performance of such duties.

"(3) The Commission shall meet at the call of the Chairman or at the call of a majority of the members thereof.

"(c) [Personnel; experts; information from departments and agencies] (1) The Commission shall have the power to appoint and fix the compensation of such personnel as it deems advisable, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates.

"(2) The Commission may procure, in accordance with the provisions of section 3109 of title 5, United States Code, the temporary or intermittent services of experts or consultants. Persons so employed shall receive compensation at a rate to be fixed by the Commission, but not in excess of $75 per diem, including traveltime. While away from his home or regular place of business in the performance of services for the Commission, any such person may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently.

"(3) The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out its duties under this section. Upon request of the Chairman of the Commission, such department or agency shall furnish such information to the Commission.

"(d) [Marihuana study; report to the President and the Congress] (1) The Commission shall conduct a

study of marihuana including, but not limited to, the following areas:

"(A) the extent of use of marihuana in the United States to include its various sources of users, number of arrests, number of convictions, amount of marihuana seized, type of user, nature of use;

"(B) an evaluation of the efficacy of existing marihuana laws;

"(C) a study of the pharmacology of marihuana and its immediate and long-term effects, both physiological and psychological;

"(D) the relationship of marihuana use to aggressive behavior and crime.

"(E) the relationship between marihuana and the use of other drugs; and

"(F) the international control of marihuana.

"(2) Within one year after the date on which funds first become available to carry out this section, the Commission shall submit to the President and the Congress a comprehensive report on its study and investigation under this subsection which shall include its recommendations and such proposals for legislation and administrative action as may be necessary to carry out its recommendations.

"(e) [Study and investigation of causes of drug abuse; report to the President and the Congress; termination of Commission] The Commission shall conduct a comprehensive study and investigation of the causes of drug abuse and their relative significance. The Commission shall submit to the President and the Congress such interim reports as it deems advisable and shall within two years after the date on which funds first become available to carry out this section submit to the President and the Congress a final report which shall contain a detailed statement of its findings and conclusions and also such recommendations for legislation and administrative actions as it deems appropriate. The Commission shall cease to exist sixty days after the final report is submitted under this subsection.

"(f) [Limitation on expenditures] Total expenditures of the Commission shall not exceed $4,000,000."

EXECUTIVE ORDER NO. 11599

Ex. Ord. No. 11599, June 17, 1971, 36 F.R. 11793, formerly set out as a note under this section, which established the Special Action Office for Drug Abuse Prevention, was superseded by former section 1111 et seq. of this title and is now covered by section 1111 et seq. of this title, which established the Office of Drug Abuse Policy.

EXECUTIVE ORDER NO. 11641

Ex. Ord. No. 11641, Jan. 28, 1972, 37 F.R. 2421, formerly set out as a note under this section, which established the Office for Drug Abuse Law Enforcement, was revoked by Ex. Ord. No. 11727, July 6, 1973, 38 F.R. 18357, set out as a note under this section.

EXECUTIVE ORDER NO. 11676

Ex. Ord. No. 11676, July 27, 1972, 37 F.R. 15125, formerly set out as a note under this section, which established the Office of National Narcotics Intelligence, was revoked by Ex. Ord. No. 11727, July 6, 1973, 38 F.R. 18357, set out as a note under this section.

EX. ORD. NO. 11727. DRUG LAW ENFORCEMENT

Ex. Ord. No. 11727, July 6, 1973, 38 F.R. 18357, provided:

Reorganization Plan No. 2 of 1973 [set out in the Appendix to Title 5, Government Organization and Employees], which becomes effective on July 1, 1973, among other things establishes a Drug Enforcement Administration in the Department of Justice. In my message to the Congress transmitting that plan, I stated that all functions of the Office for Drug Abuse Law Enforcement (established pursuant to Executive Order No. 11641 of January 28, 1972) and the Office of National Narcotics Intelligence (established pursuant to Executive Order No. 11676 of July 27, 1972) would, together with other related functions, be merged in the new Drug Enforcement Administration.

NOW, THEREFORE, by virtue of the authority vested in me by the Constitution and laws of the United States, including section 5317 of title 5 of the United States Code, as amended, it is hereby ordered as follows:

SECTION 1. The Attorney General, to the extent permitted by law, is authorized to coordinate all activities of executive branch departments and agencies which are directly related to the enforcement of laws respecting narcotics and dangerous drugs. Each department and agency of the Federal Government shall, upon request and to the extent permitted by law, assist the Attorney General in the performance of functions assigned to him pursuant to this order, and the Attorney General may, in carrying out those functions, utilize the services of any other agencies, Federal and State, as may be available and appropriate.

SEC. 2. Executive Order No. 11641 of January 28, 1972, is revoked and the Attorney General shall provide for the reassignment of the functions of the Office for Drug Abuse Law Enforcement and for the abolishment of that Office.

SEC. 3. Executive Order No. 11676 of July 27, 1972, is hereby revoked and the Attorney General shall provide for the reassignment of the functions of the Office of National Narcotics Intelligence and for the abolishment of that Office.

SEC. 4. Section 1 of Executive Order No. 11708 of March 23, 1973, as amended [set out as a note under section 5317 of Title 5, Government Organization and Employees], placing certain positions in level IV of the Executive Schedule is hereby further amended by deleting—

(1) "(6) Director, Office for Drug Abuse Law Enforcement, Department of Justice."; and

(2) "(7) Director, Office of National Narcotics Intelligence, Department of Justice."

SEC. 5. The Attorney General shall provide for the winding up of the affairs of the two offices and for the reassignment of their functions.

SEC. 6. This order shall be effective as of July 1, 1973.

RICHARD NIXON.

§ 802. Definitions

As used in this subchapter:

(1) The term "addict" means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.

(2) The term "administer" refers to the direct application of a controlled substance to the body of a patient or research subject by—

(A) a practitioner (or, in his presence, by his authorized agent), or

(B) the patient or research subject at the direction and in the presence of the practitioner,

whether such application be by injection, inhalation, ingestion, or any other means.

(3) The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

(4) The term "Bureau of Narcotics and Dangerous Drugs" means the Bureau of Narcotics

and Dangerous Drugs in the Department of Justice.

(5) The term "control" means to add a drug or other substance, or immediate precursor, to a schedule under part B of this subchapter, whether by transfer from another schedule or otherwise.

(6) The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1954.

(7) The term "counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

(8) The terms "deliver" or "delivery" mean the actual, constructive, or attempted transfer of a controlled substance, whether or not there exists an agency relationship.

(9) The term "depressant or stimulant substance" means—

(A) a drug which contains any quantity of (i) barbituric acid or any of the salts of barbituric acid; or (ii) any derivative of barbituric acid which has been designated by the Secretary as habit forming under section 352(d) of this title; or

(B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous systems; or

(C) lysergic acid diethylamide; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance. The term "distributor" means a person who so delivers a controlled substance.

(12) The term "drug" has the meaning given that term by section 321(g)(1) of this title.

(13) The term "felony" means any Federal or State offense classified by applicable Federal or State law as a felony.

(14) The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.

(15) The term "marihuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

(16) The term "narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, coca leaves, and opiates.

(B) A compound, manufacture, salt, derivative, or preparation of opium, coca leaves, or opiates.

(C) A substance (and any compound, manufacture, salt, derivative, or preparation thereof) which is chemically identical with any of the substances referred to in clause (A) or (B).

Such term does not include decocainized coca leaves or extracts of coca leaves which extracts do not contain cocaine or ecgonine.

(17) The term "opiate" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

(18) The term "opium poppy" means the plant of the species Papaver somniferum L., except the seed thereof.

(19) The term "poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(20) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which

he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(21) The term "production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(22) The term "immediate precursor" means a substance—

(A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.

(23) The term "Secretary", unless the context otherwise indicates, means the Secretary of Health, Education, and Welfare.

(24) The term "State" means any State, territory, or possession of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the Canal Zone.

(25) The term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

(26) The term "United States", when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.

(27) The term "maintenance treatment" means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

(28) The term "detoxification treatment" means the dispensing, for a period not in excess of twenty-one days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

(Pub. L. 91-513, title II, § 102, Oct. 27, 1970, 84 Stat. 1242; Pub. L. 93-281, § 2, May 14, 1974, 88 Stat. 124.)

REFERENCES IN TEXT

"This subchapter", referred to in text, was in the original "this title" which is title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, and is popularly known as the "Controlled Substances Act". For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables volume.

AMENDMENTS

1974—Pars. (27), (28). Pub. L. 93-281 added pars. (27) and (28).

TRANSFER OF FUNCTIONS

The Bureau of Narcotics and Dangerous Drugs, including the office of Director thereof, in the Department of Justice was abolished by Reorg. Plan No. 2 of 1973, eff. July 1, 1973, 38 F.R. 15932, 87 Stat. 1091, set out in the Appendix to Title 5, Government Organization and Employees. Reorg. Plan No. 2 of 1973 also created in the Department of Justice a single, comprehensive agency for the enforcement of drug laws to be known as the Drug Enforcement Administration, empowered the Attorney General to authorize the performance by officers, employees, and agencies of the Department of functions transferred to him, and directed the Attorney General to coordinate all drug law enforcement functions to assure maximum cooperation between the Drug Enforcement Administration, the Federal Bureau of Investigation, and the other units of the Department of Justice involved in drug law enforcement.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 822, 951, 957, 1118 of this title; title 18 sections 1952, 4251; title 19 section 1584; title 26 section 7607; title 28 section 2901; title 29 section 1111; title 31 section 1034; title 42 sections 201, 3411; title 46 section 239a.

§ 803. Increase in numbers of enforcement personnel; authorization of appropriations

(a) During the fiscal year 1971, the Bureau of Narcotics and Dangerous Drugs is authorized to add at least 300 agents, together with necessary supporting personnel, to the number of enforcement personnel currently available to it.

(b) There are authorized to be appropriated not to exceed $6,000,000 for the fiscal year 1971 and for each fiscal year thereafter to carry out the provisions of subsection (a) of this section.

(Pub. L. 91-513, title II, § 103, Oct. 27, 1970, 84 Stat. 1245.)

TRANSFER OF FUNCTIONS

For abolition of the Bureau of Narcotics and Dangerous Drugs, including the Office of Director thereof, and creation of a single comprehensive agency for the enforcement of drug laws by Reorg. Plan No. 2 of 1973, eff. July 1, 1973, 38 F.R. 15932, 87 Stat. 1091, see Transfer of Functions note set out under section 802 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 904 of this title.

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

§ 811. Authority and criteria for classification of substances

(a) Rules and regulations of Attorney General; hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e) of this section, the Attorney General may by rule—

(1) add to such a schedule or transfer between such schedules any drug or other substance if he—

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

(c) Factors determinative of control or removal from schedules

In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

(d) International treaties, conventions, and protocols requiring control

If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section.

(e) Immediate precursors

The Attorney General may, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. If the Attorney General designates a substance as an immediate precursor and places it in a schedule, other substances shall not be placed in a schedule solely because they are its precursors.

(f) Abuse potential

If, at the time a new-drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.

(g) Non-narcotic substances sold over the counter without a prescription; dextromethorphan

(1) The Attorney General shall by regulation exclude any non-narcotic substance from a schedule if such substance may, under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], be lawfully sold over the counter without a prescription.

(2) Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this subchapter unless controlled after October 27, 1970 pursuant to the foregoing provisions of this section.

(Pub. L. 91-513, title II, § 201, Oct. 27, 1970, 84 Stat. 1245.)

REFERENCES IN TEXT

"This subchapter", referred to in subsecs. (a), (c)(8), and (g)(2), was in the original "this title" which is title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, and is popularly known as the "Controlled Substances Act". For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables volume.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (g)(1), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 812, 872, 1118 of this title.

§ 812. Schedules of controlled substances

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970 and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) SCHEDULE I.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) SCHEDULE II.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) SCHEDULE III.—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) SCHEDULE IV.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) SCHEDULE V.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Initial schedules of controlled substances

Schedules I, II, III, IV, and V shall, unless and until amended pursuant to section 811 of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

SCHEDULE I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.
(2) Allylprodine.
(3) Alphacetylmathadol.
(4) Alphameprodine.
(5) Alphamethadol.
(6) Benzethidine.
(7) Betacetylmethadol.
(8) Betameprodine.
(9) Betamethadol.
(10) Betaprodine.
(11) Clonitazene.
(12) Dextromoramide.
(13) Dextrorphan.
(14) Diampromide.
(15) Diethylthiambutene.
(16) Dimenoxadol.
(17) Dimepheptanol.
(18) Dimethylthiambutene.
(19) Dioxaphetyl butyrate.
(20) Dipipanone.
(21) Ethylmethylthiambutene.
(22) Etonitazene.
(23) Etoxeridine.
(24) Furethidine.
(25) Hydroxypethidine.
(26) Ketobemidone.
(27) Levomoramide.
(28) Levophenacylmorphan.
(29) Morpheridine.
(30) Noracymethadol.
(31) Norlevorphanol.
(32) Normethadone.
(33) Norpipanone.
(34) Phenadoxone.
(35) Phenampromide.
(36) Phenomorphan.
(37) Phenoperidine.
(38) Piritramide.
(39) Propheptazine.
(40) Properidine.
(41) Racemoramide.
(42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salt of isomers whenever the existence of such salts,

isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine.
(2) Acetyldihydrocodeine.
(3) Benzylmorphine.
(4) Codeine methylbromide.
(5) Codeine-N-Oxide.
(6) Cyprenorphine.
(7) Desomorphine.
(8) Dihydromorphine.
(9) Etorphine.
(10) Heroin.
(11) Hydromorphinol.
(12) Methyldesorphine.
(13) Methylhydromorphine.
(14) Morphine methylbromide.
(15) Morphine methylsulfonate.
(16) Morphine-N-Oxide.
(17) Myrophine.
(18) Nicocodeine.
(19) Nicomorphine.
(20) Normorphine.
(21) Pholcodine.
(22) Thebacon.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine.
(2) 5-methoxy-3,4-methylenedioxy amphetamine.
(3) 3,4,5-trimethoxy amphetamine.
(4) Bufotenine.
(5) Diethyltryptamine.
(6) Dimethyltryptamine.
(7) 4-methyl-2,5-diamethoxyamphetamine.
(8) Ibogaine.
(9) Lysergic acid diethylamide.
(10) Marihuana.
(11) Mescaline.
(12) Peyote.
(13) N-ethyl-3-piperidyl benzilate.
(14) N-methyl-3-piperidyl benzilate.
(15) Psilocybin.
(16) Psilocyn.
(17) Tetrahydrocannabinols.

SCHEDULE II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is posible within the specific chemical designation:

(1) Alphaprodine.
(2) Anileridine.
(3) Bezitramide.
(4) Dihydrocodeine.
(5) Diphenoxylate.
(6) Fentanyl.
(7) Isomethadone.
(8) Levomethorphan.
(9) Levorphanol.
(10) Metazocine.
(11) Methadone.
(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane.
(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.
(14) Pethidine.
(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.
(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.
(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
(18) Phenazocine.
(19) Piminodine.
(20) Racemethorphan.
(21) Racemorphan.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

SCHEDULE III

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.
(2) Phenmetrazine and its salts.
(3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.
(4) Methylphenidate.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.

(2) Chorhexadol.
(3) Glutehimide.
(4) Lysergic acid.
(5) Lysergic acid amide.
(6) Methyprylon.
(7) Phencyclidine.
(8) Sulfondiethylmethane.
(9) Sulfonethylmethane.
(10) Sulfonmethane.

(c) Nalorphine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

SCHEDULE IV

(1) Barbital.
(2) Chloral betaine.
(3) Chloral hydrate.
(4) Ethchlorvynol.
(5) Ethinamate.
(6) Methohexital.
(7) Meprobamate.
(8) Methylphenobarbital.
(9) Paraldehyde.
(10) Petrichloral.
(11) Phenobarbital.

SCHEDULE V

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(d) Stimulants or depressants containing active medicinal ingredients; exception

The Attorney General may by regulation except any compound, mixture, or preparation containing any depressant or stimulant substance in paragraph (a) or (b) of schedule III or in schedule IV or V from the application of all or any part of this subchapter if (1) the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant or stimulant effect on the central nervous system, and (2) such ingredients are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a depressant or stimulant effect on the central nervous system.

(Pub. L. 91-513, title II, § 202, Oct. 27, 1970, 84 Stat. 1247.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 811, 1118 of this title; title 19 sections 2462, 2484.

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

§ 821. Rules and regulations

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances.

(Pub. L. 91-513, title II, § 301, Oct. 27, 1970, 84 Stat. 1253.)

§ 822. Persons required to register

(a) Annual registration

Every person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(b) Authorized activities

Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances are authorized to possess, manufacture, distribute, or dispense such substances (including any such activity in the conduct of research) to the

extent authorized by their registration and in conformity with the other provisions of this subchapter.

(c) Exceptions

The following persons shall not be required to register and may lawfully possess any controlled substance under this subchapter:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 802(25) of this title.

(d) Waiver

The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e) Separate registration

A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

(f) Inspection

The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

(Pub. L. 91-513, title II, § 302, Oct. 27, 1970, 84 Stat. 1253.)

REFERENCES IN TEXT

"This subchapter", referred to in subsecs. (b) and (c), was in the original "this title" which is title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, and is popularly known as the "Controlled Substances Act". For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables volume.

PROVISIONAL REGISTRATION

Section 703 of Pub. L. 91-513 provided that:

"(a)(1) Any person who—

"(A) is engaged in manufacturing, distributing, or dispensing any controlled substance on the day before the effective date of section 302 [this section], and

"(B) is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act [section 360 of this title] or under section 4722 of the Internal Revenue Code of 1954 [section 4722 of Title 26], shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 303 [section 823 of this title] for the manufacture, distribution, or dispensing (as the case may be) of controlled substances.

"(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 [section 360 of this title] or under such section 4722 [section 4722 of Title 26] (as the case may be) shall be his registration number for purposes of section 303 of this title [section 823 of this title].

"(b) The provisions of section 304 [section 824 of this title], relating to suspension and revocation of registration, shall apply to a provisional registration under this section.

"(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until—

"(1) the date on which such person has registered with the Attorney General under section 303 [section 823 of this title] or has had his registration denied under such section, or

"(2) such date as may be prescribed by the Attorney General for registration of manufacturers, distributors, or dispensers, as the case may be,

whichever occurs first."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 827, 828, 880, 958, 965 of this title.

§ 823. Registration requirements

(a) Manufacturers of controlled substances in schedules I and II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) Distributors of controlled substances in schedules I and II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

(d) Manufacturers of controlled substances in schedules III, IV, and V

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) Distributors of controlled substances in schedules III, IV, and V

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Research; pharmacies; research applications

Practitioners shall be registered to dispense or conduct research with controlled substances in schedule II, III, IV, or V if they are authorized to dispense or conduct research under the law of the State in which they practice. Separate registration under this part for practitioners engaging in research with nonnarcotic controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Pharmacies (as distinguished from pharmacists) when engaged in commercial activities, shall be registered to dispense controlled substances in schedule II, III, IV, or V if they are authorized to dispense under the law of the State in which they regularly conduct business. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title.

(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications

Practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(1) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(2) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (A) security of stocks of narcotic drugs for such treatment, and (B) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(3) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(Pub. L. 91-513, title II, § 303, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 93-281, § 3, May 14, 1974, 88 Stat. 124.)

AMENDMENTS

1974—Subsec. (g). Pub. L. 93-281 added subsec. (g).

PROVISIONAL REGISTRATION

For provisional registration of persons engaged in manufacturing, distributing, or dispensing of controlled substances on the day before the effective date of section 822 of this title who are registered on such date under section 360 of this title or section 4722 of Title 26, see section 703 of Pub. L. 91-513, set out as a note under section 822 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 824, 827, 828, 880, 952, 958, 965 of this title.

§ 824. Denial, revocation, or suspension of registration

(a) Grounds

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance; or

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances.

A registration pursuant to section 823(g) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g) of this title.

(b) Limits of revocation or suspension

The Attorney General may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.

(c) Service of show cause order; proceedings

Before taking action pursuant to this section, or pursuant to a denial of registration under section 823 of this title, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.

(d) Suspension of registration in cases of imminent danger

The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 823(g) of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(e) Suspension and revocation of quotas

The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 826 of this title.

(f) Disposition of controlled substances

In the event the Attorney General suspends or revokes a registration granted under section 823 of this title, all controlled substances owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances in accordance with section 881(e) of this title.

(Pub. L. 91-513, title II, § 304, Oct. 27, 1970, 84 Stat. 1255; Pub. L. 93-281, § 4, May 14, 1974, 88 Stat. 125.)

AMENDMENTS

1974—Subsec. (a). Pub. L. 93-281, § 4(a), provided for revocation or suspension of a registration pursuant to section 823(g) of this title for failure of a registrant to comply with standards referred to in such section 823(g).

Subsec. (d). Pub. L. 93-281, § 4(b), substituted in second sentence "A suspension under this subsection" for "Such suspension".

PROVISIONAL REGISTRATION

Applicability of this section to provisional registrations, see section 703 of Pub. L. 91-513, set out as a note under section 822 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 823, 842, 958 of this title.

§ 825. Labeling and packaging

(a) Symbol

It shall be unlawful to distribute a controlled substance in a commercial container unless such container, when and as required by regulations of the Attorney General, bears a label (as defined in section 321(k) of this title) containing an identifying symbol for such substance in accordance with such regulations. A different symbol shall be required for each schedule of controlled substances.

(b) Unlawful distribution without identifying symbol

It shall be unlawful for the manufacturer of any controlled substance to distribute such substance unless the labeling (as defined in section 321(m) of this title) of such substance contains, when and as required by regulations of the Attorney General, the identifying symbol required under subsection (a) of this section.

(c) Warning on label

The Secretary shall prescribe regulations under section 353(b) of this title which shall provide that the label of a drug listed in schedule II, III, or IV shall, when dispensed to or for a patient, contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient.

(d) Containers to be securely sealed

It shall be unlawful to distribute controlled substances in schedule I or II, and narcotic drugs in schedule III or IV, unless the bottle or other container, stopper, covering, or wrapper thereof is securely sealed as required by regulations of the Attorney General.

(Pub. L. 91-513, title II, § 305, Oct. 27, 1970, 84 Stat. 1256.)

EFFECTIVE DATE

Section effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, but with the Attorney General authorized to postpone such effective date for such period as he might determine to be necessary for the efficient administration of this subchapter, see section 704(c) of Pub. L. 91-513, set out as an Effective Date note under section 801 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 842, 958 of this title.

§ 826. Production quotas for controlled substances

(a) Establishment of total annual needs

The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance.

(b) Individual production quotas; revised quotas

The Attorney General shall limit or reduce individual production quotas to the extent necessary to prevent the aggregate of individual quotas from exceeding the amount determined necessary each year by the Attorney General under subsection (a) of this section. The quota of each registered manufacturer for each basic class of controlled substance in schedule I or II shall be revised in the same proportion as the limitation or reduction of the aggregate of the quotas. However, if any registrant, before the issuance of a limitation or reduction in quota, has manufactured in excess of his revised quota, the amount of the excess shall be subtracted from his quota for the following year.

(c) Manufacturing quotas for registered manufacturers

On or before October 1 of each year, upon application therefor by a registered manufacturer, the Attorney General shall fix a manufacturing quota for the basic classes of controlled substances in schedules I and II that the manufacturer seeks to produce. The quota shall be subject to the provisions of subsections (a) and (b) of this section. In fixing such quotas, the Attorney General shall determine the manufacturer's estimated disposal, inventory, and other requirements for the calendar year; and, in making his determination, the Attorney General shall consider the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the manufacturer's production cycle and inventory position, the economic availability of raw materials, yield and stability problems, emergencies such as strikes and fires, and other factors.

(d) Quotas for registrants who have not manufactured controlled substance during one or more preceding years

The Attorney General shall, upon application and subject to the provisions of subsections (a) and (b) of this section, fix a quota for a basic class of controlled substance in schedule I or II for any registrant who has not manufactured that basic class of controlled substance during one or more preceding calendar years. In fixing such quota, the Attorney General shall take into account the registrant's reasonably anticipated requirements for the current year; and, in making his determination of such requirements, he shall consider such factors specified in subsection (c) of this section as may be relevant.

(e) Quota increases

At any time during the year any registrant who has applied for or received a manufacturing quota for a basic class of controlled substance in schedule I or II may apply for an increase in that quota to meet his estimated disposal, inventory, and other requirements during the remainder of that year. In passing upon the application the Attorney General shall take into consideration any occurrences since the filing of the registrant's initial quota application that may require an increased manufacturing rate by the registrant during the balance of the year. In passing upon the application the Attorney General may also take into account the amount, if any, by which the determination of the Attorney General under subsection (a) of this section exceeds the aggregate

of the quotas of all registrants under this section.

(f) Incidental production exception

Notwithstanding any other provisions of this subchapter, no registration or quota may be required for the manufacture of such quantities of controlled substances in schedules I and II as incidentally and necessarily result from the manufacturing process used for the manufacture of a controlled substance with respect to which its manufacturer is duly registered under this subchapter. The Attorney General may, by regulation, prescribe restrictions on the retention and disposal of such incidentally produced substances.

(Pub. L. 91-513, title II, § 306, Oct. 27, 1970, 84 Stat. 1257; Pub. L. 94-273, § 3(16), Apr. 21, 1976, 90 Stat. 377.)

AMENDMENTS

1976—Subsec. (c). Pub. L. 94-273 substituted "October" for "July".

EFFECTIVE DATE

Section effective on the first day of the seventh calendar month that begins after Oct. 26, 1970, but with the Attorney General authorized to postpone such effective date for such period as he might determine to be necessary for the efficient administration of this subchapter, see section 704(c) of Pub. L. 91-513, set out as an Effective Date note under section 801 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 823, 824, 842 of this title.

§ 827. Records and reports of registrants

(a) Inventory

Except as provided in subsection (c) of this section—

(1) every registrant under this subchapter shall, on May 1, 1971, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this subchapter manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after May 1, 1971, every registrant under this subchapter manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

(b) Availability of records

Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

(c) Nonapplicability

The foregoing provisions of this section shall not apply—

(1)(A) with respect to any narcotic controlled substance in schedule II, III, IV, or V, to the prescribing or administering of such substance by a practitioner in the lawful course of his professional practice unless such substance was prescribed or administered in the course of maintenance treatment or detoxification treatment of an individual; or

(B) with respect to nonnarcotic controlled substances in schedule II, III, IV, or V, to any practitioner who dispenses such substances to his patients, unless the practitioner is regularly engaged in charging his patients, either separately or together with charges for other professional services, for substances so dispensed;

(2)(A) to the use of controlled substances, at establishments registered under this subchapter which keep records with respect to such substances, in research conducted in conformity with an exemption granted under section 355(i) or 360b(j) of this title;

(B) to the use of controlled substances, at establishments registered under this subchapter which keep records with respect to such substances, in preclinical research or in teaching; or

(3) to the extent of any exemption granted to any person, with respect to all or part of such provisions, by the Attorney General by or pursuant to regulation on the basis of a finding that the application of such provisions (or part thereof) to such person is not necessary for carrying out the purposes of this subchapter.

(d) Periodic reports to Attorney General

Every manufacturer registered under section 823 of this title shall, at such time or times and in such form as the Attorney General may require, make periodic reports to the Attorney General of every sale, delivery or other disposal by him of any controlled substance, and each distributor shall make such reports with respect to narcotic controlled substances, identifying by the registration number assigned under this subchapter the person or establishment (unless exempt from registration under section 822(d) of this title) to whom such sale, delivery, or other disposal was made.

(e) Investigational uses of drugs; procedures

Regulations under sections 355(i) and 360b(j) of this title, relating to investigational use of drugs, shall include such procedures as the Secretary, after consultation with the Attorney General, determines are necessary to insure the security and accountability of controlled substances used in research to which such regulations apply.

(Pub. L. 91-513, title II, § 307, Oct. 27, 1970, 84 Stat. 1258; Pub. L. 93-281, § 5, May 14, 1974, 88 Stat. 125.)

AMENDMENTS

1974—Subsec. (c)(1)(A). Pub. L. 93-281 substituted "any narcotic controlled substance" for "narcotic controlled substances" and made section applicable to any narcotic controlled substance prescribed or administered in the course of maintenance treatment or detoxification treatment of an individual.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 823, 829, 902, 958 of this title.

§ 828. Order forms

(a) Unlawful distribution of controlled substances

It shall be unlawful for any person to distribute a controlled substance in schedule I or II to another except in pursuance of a written order of the person to whom such substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) of this section and regulations prescribed by him pursuant to this section.

(b) Nonapplicability of provisions

Nothing in subsection (a) of this section shall apply to—

(1) the exportation of such substances from the United States in conformity with subchapter II of this chapter;

(2) the delivery of such a substance to or by a common or contract carrier for carriage in the lawful and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business; but where such carriage or storage is in connection with the distribution by the owner of the substance to a third person, this paragraph shall not relieve the distributor from compliance with subsection (a) of this section.

(c) Preservation and availability

(1) Every person who in pursuance of an order required under subsection (a) of this section distributes a controlled substance shall preserve such order for a period of two years, and shall make such order available for inspection and copying by officers and employees of the United States duly authorized for that purpose by the Attorney General, and by officers or employees of States or their political subdivisions who are charged with the enforcement of State or local laws regulating the production, or regulating the distribution or dispensing, of controlled substances and who are authorized under such laws to inspect such orders.

(2) Every person who gives an order required under subsection (a) of this section shall, at or before the time of giving such order, make or cause to be made a duplicate thereof on a form to be issued by the Attorney General in blank in accordance with subsection (d) of this section and regulations prescribed by him pursuant to this section, and shall, if such order is accepted, preserve such duplicate for a period of two years and make it available for inspection and copying by the officers and employees mentioned in paragraph (1) of this subsection.

(d) Issuance

(1) The Attorney General shall issue forms pursuant to subsections (a) and (c)(2) of this section only to persons validly registered under section 823 of this title (or exempted from registration under section 822(d) of this title). Whenever any such form is issued to a person, the Attorney General shall, before delivery thereof, insert therein the name of such person, and it shall be unlawful for any other person (A) to use such form for the purpose of obtaining controlled substances or (B) to furnish such form to any person with intent thereby to procure the distribution of such substances.

(2) The Attorney General may charge reasonable fees for the issuance of such forms in such amounts as he may prescribe for the purpose of covering the cost to the United States of issuing such forms, and other necessary activities in connection therewith.

(e) Unlawful acts

It shall be unlawful for any person to obtain by means of order forms issued under this section controlled substances for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in such substances or in the course of his professional practice or research.

(Pub. L. 91-513, title II, § 308, Oct. 27, 1970, 84 Stat. 1259.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 843 of this title.

§ 829. Prescriptions

(a) Schedule II substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act [21 U.S.C. 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled.

(b) Schedule III and IV substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 U.S.C.

353(b)]. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(c) Schedule V substances

No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

(d) Non-prescription drugs with abuse potential

Whenever it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] should be so considered because of its abuse potential, he shall so advise the Secretary and furnish to him all available data relevant thereto.

(Pub. L. 91-513, title II, § 309, Oct. 27, 1970, 84 Stat. 1260.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a), (b), and (d), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 842, 902 of this title.

PART D—OFFENSES AND PENALTIES

§ 841. Prohibited acts A

(a) Unlawful acts

Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

(b) Penalties

Except as otherwise provided in section 845 of this title, any person who violates subsection (a) of this section shall be sentenced as follows:

(1)(A) In the case of a controlled substance in schedule I or II which is a narcotic drug, such person shall be sentenced to a term of imprisonment of not more than 15 years, a fine of not more than $25,000, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 30 years, a fine of not more than $50,000, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a special parole term of at least 6 years in addition to such term of imprisonment.

(B) In the case of a controlled substance in schedule I or II which is not a narcotic drug or in the case of any controlled substance in schedule III, such person shall be sentenced to a term of imprisonment of not more than 5 years, a fine of not more than $15,000, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine of not more than $30,000, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a special parole term of at least 4 years in addition to such term of imprisonment.

(2) In the case of a controlled substance in schedule IV, such person shall be sentenced to a term of imprisonment of not more than 3 years, a fine of not more than $10,000, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 6 years, a fine of not more than $20,000, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a special parole term of at least one year in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a special parole term of at least 2 years in addition to such term of imprisonment.

(3) In the case of a controlled substance in schedule V, such person shall be sentenced to a term of imprisonment of not more than one year, a fine of not more than $5,000, or both. If any person commits such a violation after one or more convictions of him for an offense punishable under this paragraph, or for a crime under any other provision of this subchapter or subchapter II of this chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine of not more than $10,000, or both.

(4) Notwithstanding paragraph (1)(B) of this subsection, any person who violates subsection (a) of this section by distributing a small amount of marihuana for no remuneration shall be treated as provided in subsections (a) and (b) of section 844 of this title.

(c) Special parole term

A special parole term imposed under this section or section 845 of this title may be revoked

if its terms and conditions are violated. In such circumstances the original term of imprisonment shall be increased by the period of the special parole term and the resulting new term of imprisonment shall not be diminished by the time which was spent on special parole. A person whose special parole term has been revoked may be required to serve all or part of the remainder of the new term of imprisonment. A special parole term provided for in this section or section 845 of this title shall be in addition to, and not in lieu of, any other parole provided for by law.

(Pub. L. 91-513, title II, § 401, Oct. 27, 1970, 84 Stat. 1260.)

REFERENCES IN TEXT

"This subchapter", referred to in subsecs. (a), (b)(1) to (3), was in the original "this title" which is title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, and is popularly known as the "Controlled Substances Act". For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 845 of this title.

§ 842. Prohibited acts B

(a) Unlawful acts

It shall be unlawful for any person—

(1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title;

(2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;

(3) who is a registrant to distribute a controlled substance in violation of section 825 of this title;

(4) to remove, alter, or obliterate a symbol or label required by section 825 of this title;

(5) to refuse or fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter;

(6) to refuse any entry into any premises or inspection authorized by this subchapter or subchapter II of this chapter;

(7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to section 824(f) or 881 of this title or to remove or dispose of substances so placed under seal; or

(8) to use, to his own advantage, or to reveal, other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this subchapter or subchapter II of this chapter, any information acquired in the course of an inspection authorized by this subchapter concerning any method or process which as a trade secret is entitled to protection.

(b) Manufacture

It shall be unlawful for any person who is a registrant to manufacture a controlled substance in schedule I or II which is—

(1) not expressly authorized by his registration and by a quota assigned to him pursuant to section 826 of this title; or

(2) in excess of a quota assigned to him pursuant to section 826 of this title.

(c) Penalties

(1) Except as provided in paragraph (2), any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. The district courts of the United States (or, where there is no such court in the case of any territory or possession of the United States, then the court in such territory or possession having the jurisdiction of a district court of the United States in cases arising under the Constitution and laws of the United States) shall have jurisdiction in accordance with section 1355 of title 28 to enforce this paragraph.

(2)(A) If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, such person shall, except as otherwise provided in subparagraph (B) of this paragraph, be sentenced to imprisonment of not more than one year or a fine of not more than $25,000, or both.

(B) If a violation referred to in subparagraph (A) was committed after one or more prior convictions of the offender for an offense punishable under this paragraph (2), or for a crime under any other provision of this subchapter or subchapter II of this chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine of $50,000, or both.

(3) Except under the conditions specified in paragraph (2) of this subsection, a violation of this section does not constitute a crime, and a judgment for the United States and imposition of a civil penalty pursuant to paragraph (1) shall not give rise to any disability or legal disadvantage based on conviction for a criminal offense.

(Pub. L. 91-513, title II, § 402, Oct. 27, 1970, 84 Stat. 1262.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 961 of this title.

§ 843. Prohibited acts C

(a) Unlawful acts

It shall be unlawful for any person knowingly or intentionally—

(1) who is a registrant to distribute a controlled substance classified in schedule I or II, in the course of his legitimate business, except pursuant to an order or an order form as required by section 828 of this title;

(2) to use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person;

(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;

(4) to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II of this chapter; or

(5) to make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit substance.

(b) Communication facility

It shall be unlawful for any person knowingly or intentionally to use any communication facility in committing or in causing or facilitating the commission of any act or acts constituting a felony under any provision of this subchapter or subchapter II of this chapter. Each separate use of a communication facility shall be a separate offense under this subsection. For purposes of this subsection, the term "communication facility" means any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures, or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication.

(c) Penalties

Any person who violates this section shall be sentenced to a term of imprisonment of not more than 4 years, a fine of not more than $30,000, or both; except that if any person commits such a violation after one or more prior convictions of him for violation of this section, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 8 years, a fine of not more than $60,000, or both.

(Pub. L. 91-513, title II, § 403, Oct. 27, 1970, 84 Stat. 1263.)

§ 844. Penalty for simple possession; conditional discharge and expunging of records for first offense

(a) It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this subchapter or subchapter II of this chapter. Any person who violates this subsection shall be sentenced to a term of imprisonment of not more than one year, a fine of not more than $5,000, or both, except that if he commits such offense after a prior conviction or convictions under this subsection have become final, he shall be sentenced to a term of imprisonment of not more than 2 years, a fine of not more than $10,000 or both.

(b)(1) If any person who has not previously been convicted of violating subsection (a) of this section, any other provision of this subchapter or subchapter II of this chapter, or any other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, is found guilty of a violation of subsection (a) of this section after trial or upon a plea of guilty, the court may, without entering a judgment of guilty and with the consent of such person, defer further proceedings and place him on probation upon such reasonable conditions as it may require and for such period, not to exceed one year, as the court may prescribe. Upon violation of a condition of the probation, the court may enter an adjudication of guilt and proceed as otherwise provided. The court may, in its discretion, dismiss the proceedings against such person and discharge him from probation before the expiration of the maximum period prescribed for such person's probation. If during the period of his probation such person does not violate any of the conditions of the probation, then upon expiration of such period the court shall discharge such person and dismiss the proceedings against him. Discharge and dismissal under this subsection shall be without court adjudication of guilt, but a nonpublic record thereof shall be retained by the Department of Justice solely for the purpose of use by the courts in determining whether or not, in subsequent proceedings, such person qualifies under this subsection. Such discharge or dismissal shall not be deemed a conviction for purposes of disqualifications or disabilities imposed by law upon conviction of a crime (including the penalties prescribed under this part for second or subsequent convictions) or for any other purpose. Discharge and dismissal under this section may occur only once with respect to any person.

(2) Upon the dismissal of such person and discharge of the proceedings against him under paragraph (1) of this subsection, such person, if he was not over twenty-one years of age at the time of the offense, may apply to the court for an order to expunge from all official records (other than the nonpublic records to be retained by the Department of Justice under paragraph (1)) all recordation relating to his arrest, indictment or information, trial, finding of guilty, and dismissal and discharge pursuant to this section. If the court determines, after hearing, that such person was dismissed and the proceedings against him discharged and that he was not over twenty-one years of age at the time of the offense, it shall enter such order. The effect of such order shall be to restore such person, in the contemplation of the law, to the status he occupied before such arrest or indictment or information. No person as to whom such order has been entered shall be held thereafter under any provision of any law to be guilty of perjury or otherwise giving a false statement by reason of his failures to recite or acknowledge such arrest, or indictment or information, or trial in response to any inquiry made of him for any purpose.

(Pub. L. 91-513, title II, § 404, Oct. 27, 1970, 84 Stat. 1264.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 841, 885 of this title.

§ 845. Distribution to persons under age twenty-one

(a) Any person at least eighteen years of age who violates section 841(a)(1) of this title by distributing a controlled substance to a person under twenty-one years of age is (except as provided in subsection (b) of this section) punishable by (1) a term of imprisonment, or a fine, or both, up to twice that authorized by section 841(b) of this title, and (2) at least twice any special parole term authorized by section 841(b) of this title, for a first offense involving the same controlled substance and schedule.

(b) Any person at least eighteen years of age who violates section 841(a)(1) of this title by distributing a controlled substance to a person under twenty-one years of age after a prior conviction or convictions under subsection (a) of this section (or under section 333(b) of this title as in effect prior to May 1, 1971) have become final, is punishable by (1) a term of imprisonment, or a fine, or both, up to three times that authorized by section 841(b) of this title, and (2) at least three times any special parole term authorized by section 841(b) of this title, for a second or subsequent offense involving the same controlled substance and schedule.

(Pub. L. 91-513, title II, § 405, Oct. 27, 1970, 84 Stat. 1265.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 841 of this title.

§ 846. Attempt and conspiracy

Any person who attempts or conspires to commit any offense defined in this subchapter is punishable by imprisonment or fine or both which may not exceed the maximum punishment prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

(Pub. L. 91-513, title II, § 406, Oct. 27, 1970, 84 Stat. 1265.)

§ 847. Additional penalties

Any penalty imposed for violation of this subchapter shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

(Pub. L. 91-513, title II, § 407, Oct. 27, 1970, 84 Stat. 1265.)

§ 848. Continuing criminal enterprise

(a) Penalties; forfeitures

(1) Any person who engages in a continuing criminal enterprise shall be sentenced to a term of imprisonment which may not be less than 10 years and which may be up to life imprisonment, to a fine of not more than $100,000, and to the forfeiture prescribed in paragraph (2); except that if any person engages in such activity after one or more prior convictions of him under this section have become final, he shall be sentenced to a term of imprisonment which may not be less than 20 years and which may be up to life imprisonment, to a fine of not more than $200,000, and to the forfeiture prescribed in paragraph (2).

(2) Any person who is convicted under paragraph (1) of engaging in a continuing criminal enterprise shall forfeit to the United States—

(A) the profits obtained by him in such enterprise, and

(B) any of his interest in, claim against, or property or contractual rights of any kind affording a source of influence over, such enterprise.

(b) Continuing criminal enterprise defined

For purposes of subsection (a) of this section, a person is engaged in a continuing criminal enterprise if—

(1) he violates any provision of this subchapter or subchapter II of this chapter the punishment for which is a felony, and

(2) such violation is a part of a continuing series of violations of this subchapter or subchapter II of this chapter—

(A) which are undertaken by such person in concert with five or more other persons with respect to whom such person occupies a position of organizer, a supervisory position, or any other position of management, and

(B) from which such person obtains substantial income or resources.

(c) Suspension of sentence and probation prohibited

In the case of any sentence imposed under this section, imposition or execution of such sentence shall not be suspended, probation shall not be granted, and section 4202 of title 18 and the Act of July 15, 1932 (D.C. Code, secs. 24-203—24-207), shall not apply.

(d) Jurisdiction of courts

The district courts of the United States (including courts in the territories or possessions of the United States having jurisdiction under subsection (a) of this section) shall have jurisdiction to enter such restraining orders or prohibitions, or to take such other actions, including the acceptance of satisfactory performance bonds, in connection with any property or other interest subject to forfeiture under this section, as they shall deem proper.

(Pub. L. 91-513, title II, § 408, Oct. 27, 1970, 84 Stat. 1265.)

§ 849. Dangerous special drug offender sentencing

(a) Notice to court by United States Attorney

Whenever a United States attorney charged with the prosecution of a defendant in a court of the United States for an alleged felonious violation of any provision of this subchapter or subchapter II of this chapter committed when the defendant was over the age of twenty-one years has reasons to believe that the defendant is a dangerous special drug offender such United States attorney, a reasonable time before trial or acceptance by the court of a plea of guilty or nolo contendere, may sign and file with the court, and may amend, a notice (1) specifying that the defendant is a dangerous special drug offender who upon conviction of such felonious violation is subject to the imposition of a sentence under subsection (b) of this section, and (2) setting out with particularity the reasons why such attorney believes the de-

fendant to be a dangerous special drug offender. In no case shall the fact that the defendant is alleged to be a dangerous special drug offender be an issue upon the trial of such felonious violation, be disclosed to the jury, or be disclosed before any plea of guilty or nolo contendere or verdict or finding of guilty to the presiding judge without the consent of the parties. If the court finds that the filing of the notice as a public record may prejudice fair consideration of a pending criminal matter, it may order the notice sealed and the notice shall not be subject to subpena or public inspection during the pendency of such criminal matter, except on order of the court, but shall be subject to inspection by the defendant alleged to be a dangerous special drug offender and his counsel.

(b) Hearing; inspection of presentence report; counsel; process; examination of witnesses; penalty; sentence

Upon any plea of guilty or nolo contendere or verdict or finding of guilty of the defendant of such felonious violation, a hearing shall be held, before sentence is imposed, by the court sitting without a jury. The court shall fix a time for the hearing, and notice thereof shall be given to the defendant and the United States at least ten days prior thereto. The court shall permit the United States and counsel for the defendant, or the defendant if he is not represented by counsel, to inspect the presentence report sufficiently prior to the hearing as to afford a reasonable opportunity for verification. In extraordinary cases, the court may withhold material not relevant to a proper sentence, diagnostic opinion which might seriously disrupt a program of rehabilitation, any source of information obtained on a promise of confidentiality, and material previously disclosed in open court. A court withholding all or part of a presentence report shall inform the parties of its action and place in the record the reasons therefor. The court may require parties inspecting all or part of a presentence report to give notice of any part thereof intended to be controverted. In connection with the hearing, the defendant and the United States shall be entitled to assistance of counsel, compulsory process, and cross-examination of such witnesses as appear at the hearing. A duly authenticated copy of a former judgment or commitment shall be prima facie evidence of such former judgment or commitment. If it appears by a preponderance of the information, including information submitted during the trial of such felonious violation and the sentencing hearing and so much of the presentence report as the court relies upon, that the defendant is a dangerous special drug offender, the court shall sentence the defendant to imprisonment for an appropriate term not to exceed twenty-five years and not disproportionate in severity to the maximum term otherwise authorized by law for such felonious violation. Otherwise it shall sentence the defendant in accordance with the law prescribing penalties for such felonious violation. The court shall place in the record its findings, including an identification of the information relied upon in making such findings, and its reasons for the sentence imposed.

(c) Sentences for life or for a term exceeding twenty-five years

This section shall not prevent the imposition and execution of a sentence of imprisonment for life or for a term exceeding twenty-five years upon any person convicted of an offense so punishable.

(d) Mandatory minimum penalties

Notwithstanding any other provision of this section, the court shall not sentence a dangerous special drug offender to less than any mandatory minimum penalty prescribed by law for such felonious violation. This section shall not be construed as creating any mandatory minimum penalty.

(e) Special drug offender defined

A defendant is a special drug offender for purposes of this section if—

(1) the defendant has previously been convicted in courts of the United States or a State or any political subdivision thereof for two or more offenses involving dealing in controlled substances, committed on occasions different from one another and different from such felonious violation, and punishable in such courts by death or imprisonment in excess of one year, for one or more of such convictions the defendant has been imprisoned prior to the commission of such felonious violation, and less than five years have elapsed between the commission of such felonious violation and either the defendant's release, or parole or otherwise, from imprisonment for one such conviction or his commission of the last such previous offense or another offense involving dealing in controlled substances and punishable by death or imprisonment in excess of one year under applicable laws of the United States or a State or any political subdivision thereof; or

(2) the defendant committed such felonious violation as part of a pattern of dealing in controlled substances which was criminal under applicable laws of any jurisdiction, which constituted a substantial source of his income, and in which he manifested special skill or expertise; or

(3) such felonious violation was, or the defendant committed such felonious violation in furtherance of, a conspiracy with three or more other persons to engage in a pattern of dealing in controlled substances which was criminal under applicable laws of any jurisdiction, and the defendant did, or agreed that he would, initiate, organize, plan, finance, direct, manage, or supervise all or part of such conspiracy or dealing, or give or receive a bribe or use force in connection with such dealing.

A conviction shown on direct or collateral review or at the hearing to be invalid or for which the defendant has been pardoned on the ground of innocence shall be disregarded for purposes of paragraph (1) of this subsection. In support of findings under paragraph (2) of this subsection, it may be shown that the defendant has had in his own name or under his control income or property not explained as derived from a source other than such dealing. For purposes of paragraph (2) of this subsection, a substantial source of income means a source of income which for any period of one year or

more exceeds the minimum wage, determined on the basis of a forty-hour week and fifty-week year, without reference to exceptions, under section 206(a)(1) of title 29 for an employee engaged in commerce or in the production of goods for commerce, and which for the same period exceeds fifty percent of the defendant's declared adjusted gross income under section 62 of title 26. For purposes of paragraph (2) of this subsection, special skill or expertise in such dealing includes unusual knowledge, judgment or ability, including manual dexterity, facilitating the initiation, organizing, planning, financing, direction, management, supervision, execution or concealment of such dealing, the enlistment of accomplices in such dealing, the escape from detection or apprehension for such dealing, or the disposition of the fruits or proceeds of such dealing. For purposes of paragraphs (2) and (3) of this subsection, such dealing forms a pattern if it embraces criminal acts that have the same or similar purposes, results, participants, victims, or methods of commission, or otherwise are interrelated by distinguishing characteristics and are not isolated events.

(f) Dangerous defendants

A defendant is dangerous for purposes of this section if a period of confinement longer than that provided for such felonious violation is required for the protection of the public from further criminal conduct by the defendant.

(g) Appeal

The time for taking an appeal from a conviction for which sentence is imposed after proceedings under this section shall be measured from imposition of the original sentence.

(h) Review of sentence

With respect to the imposition, correction, or reduction of a sentence after proceedings under this section, a review of the sentence on the record of the sentencing court may be taken by the defendant or the United States to a court of appeals. Any review of the sentence taken by the United States shall be taken at least five days before expiration of the time for taking a review of the sentence or appeal of the conviction by the defendant and shall be diligently prosecuted. The sentencing court may, with or without motion and notice, extend the time for taking a review of the sentence for a period not to exceed thirty days from the expiration of the time otherwise prescribed by law. The court shall not extend the time for taking a review of the sentence by the United States after the time has expired. A court extending the time for taking a review of the sentence by the United States shall extend the time for taking a review of the sentence or appeal of the conviction by the defendant for the same period. The taking of a review of the sentence by the United States shall be deemed the taking of a review of the sentence and an appeal of the conviction by the defendant. Review of the sentence shall include review of whether the procedure employed was lawful, the findings made were clearly erroneous, or the sentencing court's discretion was abused. The court of appeals on review of the sentence may, after considering the record, including the entire presentence report, information—submitted during the trial of such felonious violation and the sentencing hearing, and the findings and reasons of the sentencing court, affirm the sentence, impose or direct the imposition of any sentence which the sentencing court could originally have imposed, or remand for further sentencing proceedings and imposition of sentence, except that a sentence may be made more severe only on review of the sentence taken by the United States and after hearing. Failure of the United States to take a review of the imposition of the sentence shall, upon review taken by the United States of the correction or reduction of the sentence, foreclose imposition of a sentence more severe than that previously imposed. Any withdrawal or dismissal of review of the sentence taken by the United States shall foreclose imposition of a sentence more severe than that reviewed but shall not otherwise foreclose the review of the sentence or the appeal of the conviction. The court of appeals shall state in writing the reasons for its disposition of the review of the sentence. Any review of the sentence taken by the United States may be dismissed on a showing of the abuse of the right of the United States to take such review.

(Pub. L. 91-513, title II, § 409, Oct. 27, 1970, 84 Stat. 1266.)

§ 850. Information for sentencing

Except as otherwise provided in this subchapter or section 242a(a) of title 42, no limitation shall be placed on the information concerning the background, character, and conduct of a person convicted of an offense which a court of the United States may receive and consider for the purpose of imposing an appropriate sentence under this subchapter or subchapter II of this chapter.

(Pub. L. 91-513, title II, § 410, Oct. 27, 1970, 84 Stat. 1269.)

§ 851. Proceedings to establish prior convictions

(a) Information filed by United States Attorney

(1) No person who stands convicted of an offense under this part shall be sentenced to increased punishment by reason of one or more prior convictions, unless before trial, or before entry of a plea of guilty, the United States attorney files an information with the court (and serves a copy of such information on the person or counsel for the person) stating in writing the previous convictons to be relied upon. Upon a showing by the United States attorney that facts regarding prior convictions could not with due diligence be obtained prior to trial or before entry of a plea of guilty, the court may postpone the trial or the taking of the plea of guilty for a reasonable period for the purpose of obtaining such facts. Clerical mistakes in the information may be amended at any time prior to the pronouncement of sentence.

(2) An information may not be filed under this section if the increased punishment which may be imposed is imprisonment for a term in excess of three years unless the person either waived or was afforded prosecution by indictment for the offense for which such increased punishment may be imposed.

(b) Affirmation or denial of previous conviction

If the United States attorney files an information under this section, the court shall after conviction but before pronouncement of sentence inquire of the person with respect to whom the information was filed whether he affirms or denies that he has been previously convicted as alleged in the information, and shall inform him that any challenge to a prior conviction which is not made before sentence is imposed may not thereafter be raised to attack the sentence.

(c) Denial; written response; hearing

(1) If the person denies any allegation of the information of prior conviction, or claims that any conviction alleged is invalid, he shall file a written response to the information. A copy of the response shall be served upon the United States attorney. The court shall hold a hearing to determine any issues raised by the response which would except the person from increased punishment. The failure of the United States attorney to include in the information the complete criminal record of the person or any facts in addition to the convictions to be relied upon shall not constitute grounds for invalidating the notice given in the information required by subsection (a)(1) of this section. The hearing shall be before the court without a jury and either party may introduce evidence. Except as otherwise provided in paragraph (2) of this subsection, the United States attorney shall have the burden of proof beyond a reasonable doubt on any issue of fact. At the request of either party, the court shall enter findings of fact and conclusions of law.

(2) A person claiming that a conviction alleged in the information was obtained in violation of the Constitution of the United States shall set forth his claim, and the factual basis therefor, with particularity in his response to the information. The person shall have the burden of proof by a preponderance of the evidence on any issue of fact raised by the response. Any challenge to a prior conviction, not raised by response to the information before an increased sentence is imposed in reliance thereon, shall be waived unless good cause be shown for failure to make a timely challenge.

(d) Imposition of sentence

(1) If the person files no response to the information, or if the court determines, after hearing, that the person is subject to increased punishment by reason of prior convictions, the court shall proceed to impose sentence upon him as provided by this part.

(2) If the court determines that the person has not been convicted as alleged in the information, that a conviction alleged in the information is invalid, or that the person is otherwise not subject to an increased sentence as a matter of law, the court shall, at the request of the United States attorney, postpone sentence to allow an appeal from that determination. If no such request is made, the court shall impose sentence as provided by this part. The person may appeal from an order postponing sentence as if sentence had been pronounced and a final judgment of conviction entered.

(e) Statute of limitations

No person who stands convicted of an offense under this part may challenge the validity of any prior conviction alleged under this section which occurred more than five years before the date of the information alleging such prior conviction.

(Pub. L. 91-513, title II, § 411, Oct. 27, 1970, 84 Stat. 1269.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 962 of this title.

PART E—ADMINISTRATIVE AND ENFORCEMENT PROVISONS

PART REFERRED TO IN OTHER SECTIONS

This part is referred to in section 965 of this title.

§ 871. Attorney General

(a) Delegation of functions

The Attorney General may delegate any of his functions under this subchapter to any officer or employee of the Department of Justice.

(b) Rules and regulations

The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.

(c) Acceptance of devices, bequests, gifts, and donations

The Attorney General may accept in the name of the Department of Justice any form of device, bequest, gift, or donation where the donor intends to donate property for the purpose of preventing or controlling the abuse of controlled substances. He may take all appropriate steps to secure possession of such property and may sell, assign, transfer, or convey any such property other than moneys.

(Pub. L. 91-513, title II, § 501, Oct. 27, 1970, 84 Stat. 1270.)

REFERENCES IN TEXT

"This subchapter", referred to in subsecs. (a) and (b), was in the original "this title" which is title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, and is popularly known as the "Controlled Substances Act". For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables volume.

§ 872. Education and research programs of the Attorney General

(a) Authorization

The Attorney General is authorized to carry out educational and research programs directly related to enforcement of the laws under his jurisdiction concerning drugs or other substances which are or may be subject to control under this subchapter. Such programs may include—

(1) educational and training programs on drug abuse and controlled substances law enforcement for local, State, and Federal personnel;

(2) studies or special projects designed to compare the deterrent effects of various enforcement strategies on drug use and abuse;

(3) studies or special projects designed to assess and detect accurately the presence in

the human body of drugs or other substances which are or may be subject to control under this subchapter, including the development of rapid field identification methods which would enable agents to detect microquantities of such drugs or other substances;

(4) studies or special projects designed to evaluate the nature and sources of the supply of illegal drugs throughout the country;

(5) studies or special projects to develop more effective methods to prevent diversion of controlled substances into illegal channels; and

(6) studies or special projects to develop information necessary to carry out his functions under section 811 of this title.

(b) Contracts

The Attorney General may enter into contracts for such educational and research activities without performance bonds and without regard to section 5 of title 41.

(c) Identification of research populations; authorization to withhold

The Attorney General may authorize persons engaged in research to withhold the names and other identifying characteristics of persons who are the subjects of such research. Persons who obtain this authorization may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify the subjects of research for which such authorization was obtained.

(d) Use of controlled substances in research

The Attorney General, on his own motion or at the request of the Secretary, may authorize the possession, distribution, and dispensing of controlled substances by persons engaged in research. Persons who obtain this authorization shall be exempt from State or Federal prosecution for possession, distribution, and dispensing of controlled substances to the extent authorized by the Attorney General.

(Pub. L. 91-513, title II, § 502, Oct. 27, 1970, 84 Stat. 1271.)

§ 873. Cooperative arrangements

(a) The Attorney General shall cooperate with local, State, and Federal agencies concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, he is authorized to—

(1) arrange for the exchange of information between governmental officials concerning the use and abuse of controlled substances;

(2) cooperate in the institution and prosecution of cases in the courts of the United States and before the licensing boards and courts of the several States;

(3) conduct training programs on controlled substance law enforcement for local, State, and Federal personnel;

(4) maintain in the Department of Justice a unit which will accept, catalog, file, and otherwise utilize all information and statistics, including records of controlled substance abusers and other controlled substance law offenders, which may be received from Federal, State, and local agencies, and make such information available for Federal, State, and local law enforcement purposes; and

(5) conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substances may be extracted.

(b) When requested by the Attorney General, it shall be the duty of any agency or instrumentality of the Federal Government to furnish assistance, including technical advice, to him for carrying out his functions under this subchapter; except that no such agency or instrumentality shall be required to furnish the name of, or other identifying information about, a patient or research subject whose identity it has undertaken to keep confidential.

(Pub. L. 91-513, title II, § 503, Oct. 27, 1970, 84 Stat. 1271.)

§ 874. Advisory committees

The Attorney General may from time to time appoint committees to advise him with respect to preventing and controlling the abuse of controlled substances. Members of the committees may be entitled to receive compensation at the rate of $100 for each day (including traveltime) during which they are engaged in the actual performance of duties. While traveling on official business in the performance of duties for the committees, members of the committees shall be allowed expenses of travel, including per diem instead of subsistence, in accordance with subchapter I of chapter 57 of title 5.

(Pub. L. 91-513, title II, § 504, Oct. 27, 1970, 84 Stat. 1272.)

TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of two year period following Jan. 5, 1973, and advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of two year period beginning on the date of their establishment, unless in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such two year period, or in the case of a committee established by Congress, its duration is otherwise provided by law, see section 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

§ 875. Administrative hearings

(a) In carrying out his functions under this subchapter, the Attorney General may hold hearings, sign and issue subpenas, administer oaths, examine witnesses, and receive evidence at any place in the United States.

(b) Except as otherwise provided in this subchapter, notice shall be given and hearings shall be conducted under appropriate procedures of subchapter II of chapter 5 of title 5.

(Pub. L. 91-513, title II, § 505, Oct. 27, 1970, 84 Stat. 1272.)

§ 876. Subpenas

(a) Authorization of use by Attorney General

In any investigation relating to his functions under this subchapter with respect to controlled substances, the Attorney General may subpena witnesses, compel the attendance and testimony of witnesses, and require the production of any records (including books, papers,

documents, and other tangible things which constitute or contain evidence) which the Attorney General finds relevant or material to the investigation. The attendance of witnesses and the production of records may be required from any place in any State or in any territory or other place subject to the jurisdiction of the United States at any designated place of hearing; except that a witness shall not be required to appear at any hearing more than 500 miles distant from the place where he was served with a subpena. Witnesses summoned under this section shall be paid the same fees and mileage that are paid witnesses in the courts of the United States.

(b) Service

A subpena issued under this section may be served by any person designated in the subpena to serve it. Service upon a natural person may be made by personal delivery of the subpena to him. Service may be made upon a domestic or foreign corporation or upon a partnership or other unincorporated association which is subject to suit under a common name, by delivering the subpena to an officer, to a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process. The affidavit of the person serving the subpena entered a true copy thereof by the person serving it shall be proof of service.

(c) Enforcement

In the case of contumacy by or refusal to obey a subpena issued to any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpenaed person is an inhabitant, or in which he carries on business or may be found, to compel compliance with the subpena. The court may issue an order requiring the subpenaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony touching the matter under investigation. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any such case may be served in any judicial district in which such person may be found.

(Pub. L. 91-513, title II, § 506, Oct. 27, 1970, 84 Stat. 1272.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 880 of this title.

§ 877. Judicial review

All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

(Pub. L. 91-513, title II, § 507, Oct. 27, 1970, 84 Stat. 1273.)

§ 878. Powers of enforcement personnel

Any officer or employee of the Bureau of Narcotics and Dangerous Drug designated by the Attorney General may—

(1) carry firearms;

(2) execute and serve search warrants, arrest warrants, administrative inspection warrants, subpenas, and summonses issued under the authority of the United States;

(3) make arrests without warrant (A) for any offense against the United States committed in his presence, or (B) for any felony, cognizable under the laws of the United States, if he has probable cause to believe that the person to be arrested has committed or is committing a felony;

(4) make seizures of property pursuant to the provisions of this subchapter; and

(5) perform such other law enforcement duties as the Attorney General may designate.

(Pub. L. 91-513, title II, § 508, Oct. 27, 1970, 84 Stat. 1273.)

TRANSFER OF FUNCTIONS

For abolition of the Bureau of Narcotics and Dangerous Drugs, including the Office of the Director thereof, and creation of a single comprehensive agency for the enforcement of drug laws by Reorg. Plan No. 2 of 1973, eff. July 1, 1973, 38 F.R. 15932, 87 Stat. 1091, see Transfer of Functions note set out under section 802 of this title.

§ 879. Search warrants

A search warrant relating to offenses involving controlled substances may be served at any time of the day or night if the judge or United States magistrate issuing the warrant is satisfied that there is probable cause to believe that grounds exist for the warrant and for its service at such time.

(Pub. L. 91-513, title II, § 509, Oct. 27, 1970, 84 Stat. 1274; Pub. L. 93-481, § 3, Oct. 26, 1974, 88 Stat. 1455.)

AMENDMENTS

1974—Subsec. (a). Pub. L. 93-481 struck out designation "(a)" preceding "A search warrant".

Subsec. (b). Pub. L. 93-481 struck out subsec. (b), which permitted officers authorized to execute search warrants to break open and enter premises under certain circumstances and which required that such officers identify themselves and give reasons and authority for their entry after such entry.

§ 880. Administrative inspections and warrants

(a) Controlled premises defined

As used in this section, the term "controlled premises" means—

(1) places where original or other records or documents required under this subchapter are kept or required to be kept, and

(2) places, including factories, warehouses, or other establishments, and conveyances, where persons registered under section 823 of this title (or exempted from registration under section 822(d) of this title) may lawfully hold, manufacture, or distribute, dispense,

administer, or otherwise dispose of controlled substances.

(b) Grant of authority; scope of inspections

(1) For the purpose of inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under this subchapter and otherwise facilitating the carrying out of his functions under this subchapter, the Attorney General is authorized, in accordance with this section, to enter controlled premises and to conduct administrative inspections thereof, and of the things specified in this section, relevant to those functions.

(2) Such entries and inspections shall be carried out through officers or employees (hereinafter referred to as "inspectors") designated by the Attorney General. Any such inspector, upon stating his purpose and presenting to the owner, operator, or agent in charge of such premises (A) appropriate credentials and (B) a written notice of his inspection authority (which notice in the case of an inspection requiring, or in fact supported by, an administrative inspection warrant shall consist of such warrant), shall have the right to enter such premises and conduct such inspection at reasonable times.

(3) Except as may otherwise be indicated in an applicable inspection warrant, the inspector shall have the right—

(A) to inspect and copy records, reports, and other documents required to be kept or made under this subchapter;

(B) to inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished drugs and other substances or materials, containers, and labeling found therein, and, except as provided in paragraph (5) of this subsection, all other things therein (including records, files, papers, processes, controls, and facilities) appropriate for verification of the records, reports, and documents referred to in clause (A) or otherwise bearing on the provisions of this subchapter; and

(C) to inventory any stock of any controlled substance therein and obtain samples of any such substance.

(4) Except when the owner, operator, or agent in charge of the controlled premises so consents in writing, no inspection authorized by this section shall extend to—

(A) financial data;

(B) sales data other than shipment data; or

(C) pricing data.

(c) Situations not requiring warrants

A warrant under this section shall not be required for the inspection of books and records pursuant to an administrative subpena issued in accordance with section 876 of this title, nor for entries and administrative inspections (including seizures of property)—

(1) with the consent of the owner, operator, or agent in charge of the controlled premises;

(2) in situations presenting imminent danger to health or safety;

(3) in situations involving inspection of conveyances where there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(4) in any other exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking; or

(5) in any other situations where a warrant is not constitutionally required.

(d) Administrative inspection warrants; issuance; execution; probable cause

Issuance and execution of administrative inspection warrants shall be as follows:

(1) Any judge of the United States or of a State court of record, or any United States magistrate, may, within his territorial jurisdiction, and upon proper oath or affirmation showing probable cause, issue warrants for the purpose of conducting administrative inspections authorized by this subchapter or regulations thereunder, and seizures of property appropriate to such inspections. For the purposes of this section, the term "probable cause" means a valid public interest in the effective enforcement of this subchapter or regulations thereunder sufficient to justify administrative inspections of the area, premises, building, or conveyance, or contents thereof, in the circumstances specified in the application for the warrant.

(2) A warrant shall issue only upon an affidavit of an officer or employee having knowledge of the facts alleged, sworn to before the judge or magistrate and establishing the grounds for issuing the warrant. If the judge or magistrate is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of such inspection, and, where appropriate, the type of property to be inspected, if any. The warrant shall identify the items or types of property to be seized, if any. The warrant shall be directed to a person authorized under subsection (b)(2) of this section to execute it. The warrant shall state the grounds for its issuance and the name of the person or persons whose affidavit has been taken in support thereof. It shall command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purpose specified, and, where appropriate, shall direct the seizure of the property specified. The warrant shall direct that it be served during normal business hours. It shall designate the judge or magistrate to whom it shall be returned.

(3) A warrant issued pursuant to this section must be executed and returned within ten days of its date unless, upon a showing by the United States of a need therefor, the judge or magistrate allows additional time in the warrant. If property is seized pursuant to a warrant, the person executing the warrant shall give to the person from whom or from whose premises the property was taken a copy of the warrant and a receipt for the property taken or shall leave the copy and receipt at the place from which the property was taken. The return of the warrant shall be made promptly and shall be accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises

the property was taken, if they are present, or in the presence of at least one credible person other than the person making such inventory, and shall be verified by the person executing the warrant. The judge or magistrate, upon request, shall deliver a copy of the inventory to the person from whom or from whose premises the property was taken and the applicant for the warrant.

(4) The judge or magistrate who has issued a warrant under this section shall attach to the warrant a copy of the return and all papers filed in connection therewith and shall file them with the clerk of the district court of the United States for the judicial district in which the inspection was made.

(Pub. L. 91-513, title II, § 510, Oct. 27, 1970, 84 Stat. 1274.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 965 of this title.

§ 881. Forfeitures

(a) Property subject

The following shall be subject to forfeiture to the United States and no property right shall exist in them:

(1) All controlled substances which have been manufactured, distributed, dispensed, or acquired in violation of this subchapter.

(2) All raw materials, products, and equipment of any kind which are used, or intended for use, in manufacturing, compounding, processing, delivering, importing, or exporting any controlled substance in violation of this subchapter.

(3) All property which is used, or intended for use, as a container for property described in paragraph (1) or (2).

(4) All conveyances, including aircraft, vehicles, or vessels, which are used, or are intended for use, to transport, or in any manner to facilitate the transportation, sale, receipt, possession, or concealment of property described in paragraph (1) or (2), except that—

(A) no conveyance used by any person as a common carrier in the transaction of business as a common carrier shall be forfeited under the provisions of this section unless it shall appear that the owner or other person in charge of such conveyance was a consenting party or privy to a violation of this subchapter or subchapter II of this chapter; and

(B) no conveyance shall be forfeited under the provisions of this section by reason of any act or omission established by the owner thereof to have been committed or omitted by any person other than such owner while such conveyance was unlawfully in the possession of a person other than the owner in violation of the criminal laws of the United States, or of any State.

(5) All books, records, and research, including formulas, microfilm, tapes, and data which are used, or intended for use, in violation of this subchapter.

(b) Seizure pursuant to Supplemental Rules for Certain Admiralty and Maritime Claims

Any property subject to forfeiture to the United States under this subchapter may be seized by the Attorney General upon process issued pursuant to the Supplemental Rules for certain Admiralty and Maritime Claims by any district court of the United States having jurisdiction over the property, except that seizure without such process may be made when—

(1) the seizure is incident to an arrest or a search under a search warrant or an inspection under an administrative inspection warrant;

(2) the property subject to seizure has been the subject of a prior judgment in favor of the United States in a criminal injunction or forfeiture proceeding under this subchapter;

(3) the Attorney General has probable cause to believe that the property is directly or indirectly dangerous to health or safety; or

(4) the Attorney General has probable cause to believe that the property has been used or is intended to be used in violation of this subchapter.

In the event of seizure pursuant to paragraph (3) or (4) of this subsection, proceedings under subsection (d) of this section shall be instituted promptly.

(c) Custody of Attorney General

Property taken or detained under this section shall not be repleviable, but shall be deemed to be in the custody of the Attorney General, subject only to the orders and decrees of the court or the official having jurisdiction thereof. Whenever property is seized under the provisions of this subchapter, the Attorney General may—

(1) place the property under seal;

(2) remove the property to a place designated by him; or

(3) require that the General Services Administration take custody of the property and remove it to an appropriate location for disposition in accordance with law.

(d) Other laws and proceedings applicable

All provisions of law relating to the seizure, summary and judicial forfeiture, and condemnation of property for violation of the customs laws; the disposition of such property or the proceeds from the sale thereof; the remission or mitigation of such forfeitures; and the compromise of claims and the award of compensation to informers in respect of such forfeitures shall apply to seizures and forfeitures incurred, or alleged to have been incurred, under the provisions of this subchapter, insofar as applicable and not inconsistent with the provisions hereof; except that such duties as are imposed upon the customs officer or any other person with respect to the seizure and forfeiture of property under the customs laws shall be performed with respect to seizures and forfeitures of property under this subchapter by such officers, agents, or other persons as may be authorized or designated for that purpose by the Attorney General, except to the extent that such duties arise from seizures and forfeitures effected by any customs officer.

(e) Disposition of forfeited property

Whenever property is forfeited under this subchapter the Attorney General may—

(1) retain the property for official use;

(2) sell any forfeited property which is not required to be destroyed by law and which is

not harmful to the public, but the proceeds from any such sale shall be used to pay all proper expenses of the proceedings for forfeiture and sale including expenses of seizure, maintenance of custody, advertising and court costs;

(3) require that the General Services Administration take custody of the property and remove it for disposition in accordance with law; or

(4) forward it to the Bureau of Narcotics and Dangerous Drugs for disposition (including delivery for medical or scientific use to any Federal or State agency under regulations of the Attorney General).

(f) Forfeiture of schedule I substances

All controlled substances in schedule I that are possessed, transferred, sold, or offered for sale in violation of the provisions of this subchapter shall be deemed contraband and seized and summarily forfeited to the United States. Similarly, all substances in schedule I, which are seized or come into the possession of the United States, the owners of which are unknown, shall be deemed contraband and summarily forfeited to the United States.

(g) Plants

(1) All species of plants from which controlled substances in schedules I and II may be derived which have been planted or cultivated in violation of this subchapter, or of which the owners or cultivators are unknown, or which are wild growths, may be seized and summarily forfeited to the United States.

(2) The failure, upon demand by the Attorney General or his duly authorized agent, of the person in occupancy or in control of land or premises upon which such species of plants are growing or being stored, to produce an appropriate registration, or proof that he is the holder thereof, shall constitute authority for the seizure and forfeiture.

(3) The Attorney General, or his duly authorized agent, shall have authority to enter upon any lands, or into any dwelling pursuant to a search warrant, to cut, harvest, carry off, or destroy such plants.

(Pub. L. 91-513, title II, § 511, Oct. 27, 1970, 84 Stat. 1276.)

REFERENCES IN TEXT

The customs laws, referred to in subsec. (d), are classified generally to Title 19, Customs Duties.

TRANSFER OF FUNCTIONS

For abolition of the Bureau of Narcotics and Dangerous Drugs, including the Office of Director thereof, and creation of a single comprehensive agency for the enforcement of drug laws by Reorg. Plan No. 2 of 1973, eff. July 1, 1973, 38 F.R. 15932, 87 Stat. 1091, see Transfer of Functions note set out under section 802 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 824, 842 of this title.

§ 882. Injunctions

(a) The district courts of the United States and all courts exercising general jurisdiction in the territories and possessions of the United States shall have jurisdiction in proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations of this subchapter.

(b) In case of an alleged violation of an injunction or restraining order issued under this section, trial shall, upon demand of the accused, be by a jury in accordance with the Federal Rules of Civil Procedure.

(Pub. L. 91-513, title II, § 512, Oct. 27, 1970, 84 Stat. 1278.)

REFERENCES IN TEXT

The Federal Rules of Civil Procedure, referred to in subsec. (a), are set out in the Appendix to Title 28, Judiciary and Judicial Procedure.

§ 883. Enforcement proceedings

Before any violation of this subchapter is reported by the Director of the Bureau of Narcotics and Dangerous Drugs to any United States attorney for institution of a criminal proceeding, the Director may require that the person against whom such proceeding is contemplated is given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

(Pub. L. 91-513, title II, § 513, Oct. 27, 1970, 84 Stat. 1278.)

TRANSFER OF FUNCTIONS

For abolition of the Bureau of Narcotics and Dangerous Drugs, including the Office of Director thereof, and creation of a single comprehensive agency for the enforcement of drug laws by Reorg. Plan No. 2 of 1973, eff. July 1, 1973, 38 F.R. 15932, 87 Stat. 1091, see Transfer of Functions note set out under section 802 of this title.

§ 884. Immunity and privilege

(a) Refusal to testify

Whenever a witness refuses, on the basis of his privilege against self-incrimination, to testify or provide other information in a proceeding before a court or grand jury of the United States, involving a violation of this subchapter, and the person presiding over the proceeding communicates to the witness an order issued under this section, the witness may not refuse to comply with the order on the basis of his privilege against self-incrimination. But no testimony or other information compelled under the order issued under subsection (b) of this section or any information obtained by the exploitation of such testimony or other information, may be used against the witness in any criminal case, including any criminal case brought in a court of a State, except a prosecution for perjury, giving a false statement, or otherwise failing to comply with the order.

(b) Order of United States District Court

In the case of any individual who has been or may be called to testify or provide other information at any proceeding before a court or grand jury of the United States, the United States district court for the judicial district in which the proceeding is or may be held shall issue, upon the request of the United States attorney for such district, an order requiring such individual to give any testimony or provide any other information which he refuses to give or provide on the basis of his privilege against self-incrimination.

(c) Request by United States Attorney

A United States attorney may, with the approval of the Attorney General or the Deputy Attorney General, or any Assistant Attorney General designated by the Attorney General, request an order under subsection (b) of this section when in his judgment—

(1) the testimony or other information from such individual may be necessary to the public interest; and

(2) such individual has refused or is likely to refuse to testify or provide other information on the basis of his privilege against self-incrimination.

(Pub. L. 91-513, title II, § 514, Oct. 27, 1970, 84 Stat. 1278.)

§ 885. Burden of proof; liabilities

(a) Exemptions and exceptions; presumption in simple possession offenses

(1) It shall not be necessary for the United States to negative any exemption or exception set forth in this subchapter in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this subchapter, and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit.

(2) In the case of a person charged under section 844(a) of this title with the possession of a controlled substance, any label identifying such substance for purposes of section 353(b)(2) of this title shall be admissible in evidence and shall be prima facie evidence that such substance was obtained pursuant to a valid prescription from a practitioner while acting in the course of his professional practice.

(b) Registration and order forms

In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this subchapter, he shall be presumed not to be the holder of such registration or form, and the burden of going forward with the evidence with respect to such registration or form shall be upon him.

(c) Use of vehicles, vessels, and aircraft

The burden of going forward with the evidence to establish that a vehicle, vessel, or aircraft used in connection with controlled substances in schedule I was used in accordance with the provisions of this subchapter shall be on the persons engaged in such use.

(d) Immunity of federal, state, local and other officials

Except as provided in section 2234 and 2235 of title 18, no civil or criminal liability shall be imposed by virtue of this subchapter upon any duly authorized Federal officer lawfully engaged in the enforcement of this subchapter, or upon any duly authorized officer of any State, territory, political subdivision thereof, the District of Columbia, or any possession of the United States, who shall be lawfully engaged in the enforcement of any law or municipal ordinance relating to controlled substances.

(Pub. L. 91-513, title II, § 515, Oct. 27, 1970, 84 Stat. 1279.)

§ 886. Payments and advances

(a) Payment to informers

The Attorney General is authorized to pay any person, from funds appropriated for the Bureau of Narcotics and Dangerous Drugs, for information concerning a violation of this subchapter, such sum or sums of money as he may deem appropriate, without reference to any moieties or rewards to which such person may otherwise be entitled by law.

(b) Reimbursement for purchase of controlled substances

Moneys expended from appropriations of the Bureau of Narcotics and Dangerous Drugs for purchase of controlled substances and subsequently recovered shall be reimbursed to the current appropriation for the Bureau.

(c) Advance of funds for enforcement purposes

The Attorney General is authorized to direct the advance of funds by the Treasury Department in connection with the enforcement of this subchapter.

(Pub. L. 91-513, title II, § 516, Oct. 27, 1970, 84 Stat. 1279.)

TRANSFER OF FUNCTIONS

For abolition of the Bureau of Narcotics and Dangerous Drugs, including the Office of the Director thereof, and creation of a single comprehensive agency for the enforcement of drug laws by Reorg. Plan No. 2 of 1973, eff. July 1, 1973, 38 F.R. 15932, 87 Stat. 1091, see Transfer of Functions note set out under section 802 of this title.

PART F—GENERAL PROVISIONS

CODIFICATION

The letter designation for this Part F was, in the original, Part G. The original Part F of title II of Pub. L. 91-513, consisting of section 601 thereof, is set out as a note under section 801 of this title. The original Part G of title II of Pub. L. 91-513 consisted of sections 701 to 709. Sections 701 to 705 amended and repealed sections in this title and in Title 18, Crimes and Criminal Procedure, and Title 42, The Public Health and Welfare, and enacted provisions set out as notes under sections 321, 801, and 822 of this title. See Tables Volume for classifications of said sections 701 to 705. Sections 706 to 709 of Pub. L. 91-513 are set out as sections 901 to 904 of this title and, for purposes of codification, comprise this Part F.

§ 901. Severability of provisions

If a provision of this chapter is held invalid, all valid provisions that are severable shall remain in effect. If a provision of this chapter is held invalid in one or more of its applications, the provision shall remain in effect in all its valid applications that are severable.

(Pub. L. 91-513, title II, § 706, Oct. 27, 1970, 84 Stat. 1284.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1236. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables volume.

§ 902. Savings provisions

Nothing in this chapter, except this part and, to the extent of any inconsistency, sections 827(e) and 829 of this title, shall be construed

as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 301 et seq.].

(Pub. L. 91-513, title II, § 707, Oct. 27, 1970, 84 Stat. 1284.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1236. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables volume.

The Federal Food, Drug, and Cosmetic Act, referred to in text, is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables volume.

§ 903. Application of State law

No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

(Pub. L. 91-513, title II, § 708, Oct. 27, 1970, 84 Stat. 1284.)

REFERENCES IN TEXT

"This subchapter", referred to in text, was in the original "this title" which is title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, and is popularly known as the "Controlled Substances Act". For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables volume.

§ 904. Authorization of appropriations

(a) There are authorized to be appropriated $105,000,000 for the fiscal year ending June 30, 1975, $175,000,000 for the fiscal year ending June 30, 1976, and $200,000,000 for the fiscal year ending June 30, 1977, for the expenses of the Department of Justice (other than its expenses incurred in connection with carrying out section 803(a) of this title) in carrying out its functions under this subchapter.

(b) No funds appropriated under any other provision of this chapter may be used for the expenses of the Department of Justice for which funds are authorized to be appropriated by subsection (a) of this section.

(Pub. L. 91-513, title II, § 709, Oct. 27, 1970, 84 Stat. 1284; Pub. L. 93-481, § 1, Oct. 26, 1974, 88 Stat. 1455.)

REFERENCES IN TEXT

"This subchapter", referred to in subsec. (a), was in the original "this title" which is title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, and is popularly known as the "Controlled Substances Act" For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables volume.

This chapter, referred to in subsec. (b), was, in the original, this Act, meaning Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1236. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables volume.

AMENDMENTS

1974—Subsec. (a). Pub. L. 93-481 designated existing provisions as subsec. (a), and in subsec. (a) as so designated, substituted authorization of appropriations for fiscal years ending June 30, 1975, June 30, 1976, and June 30, 1977, for authorization of appropriations for fiscal years ending June 30, 1972, June 30, 1973, and June 30, 1974.

Subsec. (b). Pub. L. 93-481 added subsec. (b).

SUBCHAPTER II—IMPORT AND EXPORT

CODIFICATION

This subchapter is comprised of Part A of title III of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1285. Part B of title III contains amendatory, repealing, and transitional provisions generally classified elsewhere.

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in sections 381, 824, 828, 841, 842, 843, 844, 848, 849, 850, 881 of this title; title 42 section 242.

§ 951. Definitions

(a) For purposes of this subchapter—

(1) The term "import" means, with respect to any article, any bringing in or introduction of such article into any area (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(2) The term "customs territory of the United States" has the meaning assigned to such term by general headnote 2 to the Tariff Schedules of the United States.

(b) Each term defined in section 802 of this title shall have the same meaning for purposes of this subchapter as such term has for purposes of subchapter I of this chapter.

(Pub. L. 91-513, title III, § 1001, Oct. 27, 1970, 84 Stat. 1285.)

REFERENCES IN TEXT

General headnote 2 to the Tariff Schedules of the United States, referred to in subsec. (a)(2), is set out in section 1202 of Title 19, Customs Duties.

"This subchapter" referred to in subsec. (b), was in the original "this title" meaning title III of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises this subchapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables volume.

EFFECTIVE DATE

Section 1105(a)-(c) of Pub. L. 91-513 provided that: "(a) Except as otherwise provided in this section, this title [see Short Title note under this section] shall become effective on the first day of the seventh calendar month that begins after the day immediately preceding the date of enactment [Oct. 27, 1970].

"(b) Sections 1000, 1001, 1006, 1015, 1016, 1103, 1104 [Short Title Note under this section and sections 171 note, 951, 956, 957 note, 965, and 966 of this title], and this section shall become effective upon enactment [Oct. 27, 1970].

"(c)(1) If the Attorney General, pursuant to the authority of section 704(c) of title II [set out as a note under section 801 of this title], postpones the effective date of section 306 (relating to manufacturing quotas) [section 826 of this title] for any period beyond the date specified in section 704(a) [set out as a note under section 801 of this title], and such postponement applies to narcotic drugs, the repeal of the Nar-

cotics Manufacturing Act of 1960 [sections 501 to 517 of this title] by paragraph (10) of section 1101(a) of this title is hereby postponed for the same period, except that the postponement made by this paragraph shall not apply to the repeal of sections 4, 5, 13, 15, and 16 of that Act [which were classified to sections 182, 503, 511, and 513 of this title and sections 4702, 4731, and 4731 note of Title 26, Internal Revenue Code].

"(2) Effective for any period of postponement, by paragraph (1) of this subsection, of the repeal of provisions of the Narcotics Manufacturing Act of 1960 [sections 501 to 517 of this title], that Act shall be applied subject to the following modifications:

"(A) The term 'narcotic drug' shall mean a narcotic drug as defined in section 102(16) of title II [section 802(16) of this title], and all references, in the Narcotics Manufacturing Act of 1960 [sections 501 to 517 of this title], to a narcotic drug as defined by section 4731 of the Internal Revenue Code of 1954 [section 4731 of title 26] are amended to refer to a narcotic drug as defined by such section 102(16) [section 802(16) of this title].

"(B) On and after the date prescribed by the Attorney General pursuant to clause (2) of section 703(c) of title II, [set out as a note under section 822 of this title], the requirements of a manufacturer's license with respect to a basic class of narcotic drug under the Narcotics Manufacturing Act of 1960 [sections 501 to 517 of this title], and of a registration under section 4722 of the Internal Revenue Code of 1954 [section 4722 of title 26] as a prerequisite to issuance of such a license, shall be superseded by a requirement of actual registration (as distinguished from provisional registration) as a manufacturer of that class of drug under section 303(a) of title II [section 823(a) of this title].

"(C) On and after the effective date of the repeal of such section 4722 [section 4722 of title 26] by section 1101(b)(3) of this title, but prior to the date specified in subparagraph (B) of this paragraph, the requirement of registration under such section 4722 [section 4722 of title 26] as a prerequisite of a manufacturer's license under the Narcotics Manufacturing Act of 1960 [sections 501 to 517 of this title] shall be superseded by a requirement of either (i) actual registration as a manufacturer under section 303 of title II [section 823 of this title] or (ii) provisional registration (by virtue of a preexisting registration under such section 4722) under section 703 of title II [set out as a note under section 822 of this title]."

SHORT TITLE

Section 1000 of title III of Pub. L. 91-513 provided that: "This title [enacting this subchapter, amending sections 198a and 162 of this title, section 4251 of Title 18, Crimes and Criminal Procedure, section 1584 of Title 19, Customs Duties, sections 4901, 4905, 6808, 7012, 7103, 7326, 7607, 7609, 7641, 7651, and 7655 of Title 26, Internal Revenue Code, section 2901 of Title 28, Judiciary and Judicial Procedure, sections 529d, 529e, and 529f of Title 31, Money and Finance, section 304m of Title 40, Public Buildings, Property, and Works, section 3411 of Title 42, The Public Health and Welfare, section 239a of Title 46, Shipping, and section 787 of Title 49, Transportation, repealing sections 171 to 174, 176 to 185, 188 to 188n, 191 to 193, 197, 198, 199, and 501 to 517 of this title, sections 1401 to 1407, and 3616 of Title 18, sections 4701 to 4707, 4711 to 4716, 4721 to 4726, 4731 to 4736, 4741 to 4746, 4751 to 4757, 4761, 4762, 4771 to 4776, 7237, 7238, and 7491 of Title 26, sections 529a and 529g of Title 31, section 1421m of Title 48, Territories and Insular Possessions, and enacting provisions set out as notes under this section and sections 171 and 957 of this title] may be cited as the 'Controlled Substances Import and Export Act'."

RULES AND REGULATIONS

Section 1105(d) of Pub. L. 91-513 provided:

"Any orders, rules and regulations which have been promulgated under any law affected by this title [see Short Title Note under this section] and which are in effect on the day preceding enactment of this title [Oct. 27, 1970] shall continue in effect until modified, superseded, or repealed."

§ 952. Importation of controlled substances

(a) Controlled substances in schedules I or II and narcotic drugs in schedules III, IV, or V; exceptions

It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any controlled substance in schedule I or II of subchapter I of this chapter, or any narcotic drug in schedule III, IV, or V of subchapter I of this chapter, except that—

(1) such amounts of crude opium and coca leaves as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes, and

(2) such amounts of any controlled substance in schedule I or II or any narcotic drug in schedule III, IV, or V that the Attorney General finds to be necessary to provide for the medical, scientific, or other legitimate needs of the United States—

(A) during an emergency in which domestic supplies of such substance or drug are found by the Attorney General to be inadequate, or

(B) in any case in which the Attorney General finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 823 of this title,

may be so imported under such regulations as the Attorney General shall prescribe. No crude opium may be so imported for the purpose of manufacturing heroin or smoking opium.

(b) Nonnarcotic controlled substances in schedules III, IV, or V

It shall be unlawful to import into the customs territory of the United States from any place outside thereof (but within the United States), or to import into the United States from any place outside thereof, any nonnarcotic controlled substance in schedule III, IV, or V, unless such nonnarcotic controlled substance—

(1) is imported for medical, scientific, or other legitimate uses, and

(2) is imported pursuant to such notification or declaration requirements as the Attorney General may by regulation prescribe.

(c) Coca leaves

In addition to the amount of coca leaves authorized to be imported into the United States under subsection (a) of this section, the Attorney General may permit the importation of additional amounts of coca leaves. All cocaine and ecgonine (and all salts, derivatives, and preparations from which cocaine or ecgonine may be synthesized or made) contained in such additional amounts of coca leaves imported under this subsection shall be destroyed under the supervision of an authorized representative of the Attorney General.

(Pub. L. 91-513, title III, § 1002, Oct. 27, 1970, 84 Stat. 1285.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 954, 956, 958, 960 of this title.

§ 953. Exportation of controlled substances

(a) Narcotic drugs in schedules I, II, III, or IV

It shall be unlawful to export from the United States any narcotic drug in schedule I, II, III, or IV unless—

(1) it is exported to a country which is a party to—

(A) the International Opium Convention of 1912 for the Suppression of the Abuses of Opium, Morphine, Cocaine, and Derivative Drugs, or to the International Opium Convention signed at Geneva on February 19, 1925; or

(B) the Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs concluded at Geneva, July 13, 1931, as amended by the protocol signed at Lake Success on December 11, 1946, and the protocol bringing under international control drugs outside the scope of the convention on July 13, 1931, for limiting the manufacture and regulating the distribution of narcotic drugs (as amended by the protocol signed at Lake Success on December 11, 1946), signed at Paris, November 19, 1948; or

(C) the Single Convention on Narcotic Drugs, 1961, signed at New York, March 30, 1961;

(2) such country has instituted and maintains, in conformity with the conventions to which it is a party, a system for the control of imports of narcotic drugs which the Attorney General deems adequate;

(3) the narcotic drug is consigned to a holder of such permits or licenses as may be required under the laws of the country of import, and a permit or license to import such drug has been issued by the country of import;

(4) substantial evidence is furnished to the Attorney General by the exporter that (A) the narcotic drug is to be applied exclusively to medical or scientific uses within the country of import, and (B) there is an actual need for the narcotic drug for medical or scientific uses within such country; and

(5) a permit to export the narcotic drug in each instance has been issued by the Attorney General.

(b) Exception for exportation for special scientific purposes

Notwithstanding subsection (a) of this section, the Attorney General may authorize any narcotic drug (including crude opium and coca leaves) in schedule I, II, III, or IV to be exported from the United States to a country which is a party to any of the international instruments mentioned in subsection (a) of this section if the particular drug is to be applied to a special scientific purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose.

(c) Nonnarcotic controlled substances in schedule I or II

It shall be unlawful to export from the United States any nonnarcotic controlled substance in schedule I or II unless—

(1) it is exported to a country which has instituted and maintains a system which the Attorney General deems adequate for the control of imports of such substances;

(2) the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of the country of import;

(3) substantial evidence is furnished to the Attorney General that (A) the controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country to which exported, (B) it will not be exported from such country, and (C) there is an actual need for the controlled substance for medical, scientific, or other legitimate uses within the country; and

(4) a permit to export the controlled substance in each instance has been issued by the Attorney General.

(d) Exception for exportation for special scientific purposes

Notwithstanding subsection (c) of this section, the Attorney General may authorize any nonnarcotic controlled substance in schedule I or II to be exported from the United States if the particular substance is to be applied to a special scientific purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose.

(e) Nonnarcotic controlled substances in schedule III or IV; controlled substances in schedule V

It shall be unlawful to export from the United States to any other country any nonnarcotic controlled substance in schedule III or IV or any controlled substance in schedule V unless—

(1) there is furnished (before export) to the Attorney General documentary proof that importation is not contrary to the laws or regulations of the country of destination;

(2) a special controlled substance invoice, in triplicate, accompanies the shipment setting forth such information as the Attorney General may prescribe to identify the parties to the shipment and the means of shipping, and

(3) two additional copies of the invoice are forwarded to the Attorney General before the controlled substance is exported from the United States.

(Pub. L. 91-513, title III, § 1003, Oct. 27, 1970, 84 Stat. 1286.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 954, 956, 960 of this title.

§ 954. Transshipment and in-transit shipment of controlled substances

Notwithstanding sections 952, 953, and 957 of this title—

(1) A controlled substance in schedule I may—

(A) be imported into the United States for transshipment to another country, or

(B) be transferred or transshipped from one vessel, vehicle, or aircraft to another vessel, vehicle, or aircraft within the United States for immediate exportation,

if and only if it is so imported, transferred, or transshipped (i) for scientific, medical, or other legitimate purposes in the country of destination, and (ii) with the prior written approval of the Attorney General (which shall be granted or denied within 21 days of the request).

(2) A controlled substance in schedule II, III, or IV may be so imported, transferred, or transshipped if and only if advance notice is given to the Attorney General in accordance with regulations of the Attorney General.

(Pub. L. 91-513, title III, § 1004, Oct. 27, 1970, 84 Stat. 1287.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 956, 961 of this title.

§ 955. Possession on board vessels, etc., arriving in or departing from United States

It shall be unlawful for any person to bring or possess on board any vessel or aircraft, or on board any vehicle of a carrier, arriving in or departing from the United States or the customs territory of the United States, a controlled substance in schedule I or II or a narcotic drug in schedule III or IV, unless such substance or drug is a part of the cargo entered in the manifest or part of the official supplies of the vessel, aircraft, or vehicle.

(Pub. L. 91-513, title III, § 1005, Oct. 27, 1970, 84 Stat. 1287.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 956, 960 of this title.

§ 956. Exemption authority

(a) The Attorney General may by regulation exempt from sections 952(a) and (b), 953, 954, and 955 of this title any individual who has a controlled substance (except a substance in schedule I) in his possession for his personal medical use, or for administration to an animal accompanying him, if he lawfully obtained such substance and he makes such declaration (or gives such other notification) as the Attorney General may by regulation require.

(b) The Attorney General may by regulation except any compound, mixture, or preparation containing any depressant or stimulant substance listed in paragraph (a) or (b) of schedule III or in schedule IV or V from the application of all or any part of this subchapter if (1) the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant or stimulant effect on the central nervous system, and (2) such ingredients are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a depressant or stimulant effect on the central nervous system.

(Pub. L. 91-513, title III, § 1006, Oct. 27, 1970, 84 Stat. 1288.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 957 of this title.

§ 957. Persons required to register

(a) No person may—

(1) import into the customs territory of the United States from any place outside thereof (but within the United States), or import into the United States from any place outside thereof, any controlled substance, or

(2) export from the United States any controlled substance in schedule I, II, III, or IV,

unless there is in effect with respect to such person a registration issued by the Attorney General under section 958 of this title, or unless such person is exempt from registration under subsection (b) of this section.

(b)(1) The following persons shall not be required to register under the provisions of this section and may lawfully possess a controlled substance:

(A) An agent or an employee of any importer or exporter registered under section 958 of this title if such agent or employee is acting in the usual course of his business or employment.

(B) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of his business or employment.

(C) An ultimate user who possesses such substance for a purpose specified in section 802(25) of this title and in conformity with an exemption granted under section 956(a) of this title.

(2) The Attorney General may, by regulation, waive the requirement for registration of certain importers and exporters if he finds it consistent with the public health and safety; and may authorize any such importer or exporter to possess controlled substances for purposes of importation and exportation.

(Pub. L. 91-513, title III, § 1007, Oct. 27, 1970, 84 Stat. 1288.)

PROVISIONAL REGISTRATION

Section 1104 of Pub. L. 91-513 provided that:

"(a)(1) Any person—

"(A) who is engaged in importing or exporting any controlled substance on the day before the effective date of section 1007 [May 1, 1971],

"(B) who notifies the Attorney General that he is so engaged, and

"(C) who is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act [section 360 of this title] or under section 4722 of the Internal Revenue Code of 1954 [section 4722 of title 26],

shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 1008 [section 958 of this title] for the import or export (as the case may be) of controlled substances.

"(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 or under such section 4722 (as the case may be) shall be his registration number for purposes of part A of this title [this subchapter].

"(b) The provisions of section 304 [section 824 of this title], relating to suspension and revocation of

registration, shall apply to a provisional registration under this section.

"(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until—

"(1) the date on which such person has registered with the Attorney General under section 1008 [section 958 of this title] or has had his registration denied under such section, or

"(2) such date as may be prescribed by the Attorney General for registration of importers or exporters, as the case may be,

whichever occurs first."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 954, 960, 965 of this title.

§ 958. Registration requirements

(a) Applicants to import or export controlled substances in schedule I or II

The Attorney General shall register an applicant to import or export a controlled substance in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the factors enumerated in paragraph (1) through (6) of section 823(a) of this title shall be considered.

(b) Activity limited to specified substances

Registration granted under subsection (a) of this section shall not entitle a registrant to import or export controlled substances in schedule I or II other than those specified in the registration.

(c) Applicants to import controlled substances in schedule III, IV, or V or to export controlled substances in schedule III or IV

The Attorney General shall register an applicant to import a controlled substance in schedule III, IV, or V or to export a controlled substance in schedule III or IV, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the factors enumerated in paragraphs (1) through (6) of section 823(d) of this title shall be considered.

(d) Registration period

No registration shall be issued under this subchapter for a period in excess of one year. Unless the regulations of the Attorney General otherwise provide, section 822(f), 824, 825, and 827 of this title shall apply to persons registered under this section to the same extent such sections apply to persons registered under section 823 of this title.

(e) Rules and regulations

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration of importers and exporters of controlled substances under this section.

(f) Scope of authorized activity

Persons registered by the Attorney General under this section to import or export controlled substances may import or export (and for the purpose of so importing or exporting, may possess) such substances to the extent authorized by their registration and in conformity with the other provisions of this subchapter and subchapter I of this chapter.

(g) Separate registrations for each principal place of business

A separate registration shall be required at each principal place of business where the applicant imports or exports controlled substances.

(h) Emergency situations

Except in emergency situations as described in section 952(a)(2)(A) of this title, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing a regulation under section 952(a) of this title authorizing the importation of such a substance, the Attorney General shall give manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

(Pub. L. 91-513, title III, § 1008, Oct. 27, 1970, 84 Stat. 1289.)

REFERENCES IN TEXT

"This subchapter" referred to in subsec. (f), was in the original "this title" meaning title III of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises this subchapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables volume.

SECTIONS REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 957, 965 of this title.

§ 959. Manufacture or distribution for purposes of unlawful importation

It shall be unlawful for any person to manufacture or distribute a controlled substance in schedule I or II—

(1) intending that such substance will be unlawfully imported into the United States; or

(2) knowing that such substance will be unlawfully imported into the United States.

This section is intended to reach acts of manufacture or distribution committed outside the territorial jurisdiction of the United States. Any person who violates this section shall be tried in the United States district court at the point of entry where such person enters the United States, or in the United States District Court for the District of Columbia.

(Pub. L. 91-513, title III, § 1009, Oct. 27, 1970, 84 Stat. 1289.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 960 of this title.

§ 960. Prohibited acts A

(a) Unlawful acts

Any person who—

(1) contrary to section 952, 953, or 957 of this title, knowingly or intentionally imports or exports a controlled substance,

(2) contrary to section 955 of this title, knowingly or intentionally brings or possesses on board a vessel, aircraft, or vehicle a controlled substance, or

(3) contrary to section 959 of this title, manufactures or distributes a controlled substance,

shall be punished as provided in subsection (b) of of this section.

(b) Penalties

(1) In the case of a violation under subsection (a) of this section with respect to a narcotic drug in schedule I or II, the person committing such violation shall be imprisoned not more than fifteen years, or fined not more than $25,000, or both. If a sentence under this paragraph provides for imprisonment, the sentence shall include a special parole term of not less than three years in addition to such term of imprisonment.

(2) In the case of a violation under subsection (a) of this section with respect to a controlled substance other than a narcotic drug in schedule I or II, the person committing such violation shall be imprisoned not more than five years, or be fined not more than $15,000, or both. If a sentence under this paragraph provides for imprisonment, the sentence shall, in addition to such term of imprisonment, include (A) a special parole term of not less than two years if such controlled substance is in schedule I, II, III, or (B) a special parole term of not less than one year if such controlled substance is in schedule IV.

(c) Special parole term

A special parole term imposed under this section or section 962 of this title may be revoked if its terms and conditions are violated. In such circumstances the original term of imprisonment shall be increased by the period of the special parole term and the resulting new term of imprisonment shall not be diminished by the time which was spent on special parole. A person whose special parole term has been revoked may be required to serve all or part of the remainder of the new term of imprisonment. The special term provided for in this section and in section 962 of this title is in addition to, and not in lieu of, any other parole provided for by law.

(Pub. L. 91-513, title III, § 1010, Oct. 27, 1970, 84 Stat. 1290.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 962 of this title.

§ 961. Prohibited acts B

Any person who violates section 954 of this title shall be subject to the following penalties:

(1) Except as provided in paragraph (2), any such person shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. Sections 842(c)(1) and (c)(3) of this title shall apply to any civil penalty assessed under this paragraph.

(2) If such a violation is prosecuted by an information or indictment which alleges that the violation was committed knowingly or intentionally and the trier of fact specifically finds that the violation was so committed, such person shall be sentenced to imprisonment for not more than one year or a fine of not more than $25,000 or both.

(Pub. L. 91-513, title III, § 1011, Oct. 27, 1970, 84 Stat. 1290.)

§ 962. Second or subsequent offenses

(a) Any person convicted of any offense under this subchapter is, if the offense is a second or subsequent offense, punishable by a term of imprisonment twice that otherwise authorized, by twice the fine otherwise authorized, or by both. If the conviction is for an offense punishable under section 960(b) of this title, and if it is the offender's second or subsequent offense, the court shall impose, in addition to any term of imprisonment and fine, twice the special parole term otherwise authorized.

(b) For purposes of this section, a person shall be considered convicted of a second or subsequent offense if, prior to the commission of such offense, one or more prior convictions of him for a felony under any provision of this subchapter or subchapter I of this chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant drugs, have become final.

(c) Section 851 of this title shall apply with respect to any proceeding to sentence a person under this section.

(Pub. L. 91-513, title III, § 1012, Oct. 27, 1970, 84 Stat. 1291.)

REFERENCES IN TEXT

"This subchapter" referred to in subsec. (b), was in the original "this title" meaning title III of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises this subchapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 960 of this title.

§ 963. Attempt and conspiracy

Any person who attempts or conspires to commit any offense defined in this subchapter is punishable by imprisonment or fine or both which may not exceed the maximum punishment prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

(Pub. L. 91-513, title III, § 1013, Oct. 27, 1970, 84 Stat. 1291.)

REFERENCES IN TEXT

"This subchapter" referred to in text, was in the original "this title" meaning title III of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises this subchapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables volume.

§ 964. Additional penalties

Any penalty imposed for violation of this subchapter shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

(Pub. L. 91-513, title III, § 1014, Oct. 27, 1970, 84 Stat. 1291.)

REFERENCES IN TEXT

"This subchapter" referred to in text, was in the original "this title" meaning title III of Pub. L. 91-513,

Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises this subchapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables volume.

§ 965. Applicability of Part E of Subchapter I

Part E of subchapter I of this chapter shall apply with respect to functions of the Attorney General (and of officers and employees of the Bureau of Narcotics and Dangerous Drugs) under this subchapter, to administrative and judicial proceedings under this subchapter, and to violations of this subchapter, to the same extent that such part applies to functions of the Attorney General (and such officers and employees) under subchapter I of this chapter, to such proceedings under subchapter I of this chapter, and to violations of subchapter I of this chapter. For purposes of the application of this section to section 880 of this title, any reference in such section 880 of this title to "this subchapter" shall be deemed to be a reference to this subchapter, any reference to section 823 of this title shall be deemed to be a reference to section 958 of this title, and any reference to section 822(d) of this title shall be deemed to be a reference to section 957(b)(2) of this title.

(Pub. L. 91-513, title III, § 1015, Oct. 27, 1970, 84 Stat. 1291.)

References in Text

"This subchapter" referred to in text, was in the original "this title" meaning title III of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises this subchapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables volume.

Transfer of Functions

For abolition of the Bureau of Narcotics and Dangerous Drugs, including the Office of Director thereof, and creation of a single comprehensive agency for the enforcement of drug laws by Reorg. Plan No. 2 of 1973, eff. July 1, 1973, 38 F.R. 15932, 87 Stat. 1091, see Transfer of Functions note set out under section 802 of this title.

§ 966. Authority of Secretary of the Treasury

Nothing in this chapter shall derogate from the authority of the Secretary of the Treasury under the customs and related laws.

(Pub. L. 91-513, title III, § 1016, Oct. 27, 1970, 84 Stat. 1291.)

References in Text

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1236. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables volume.

The customs laws, referred to in text, are classified generally to Title 19, Customs Duties.

CHAPTER 14—ALCOHOL AND DRUG ABUSE EDUCATIONAL PROGRAMS AND ACTIVITIES

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1004. Technical assistance.
1005. Payments in installments and in advance or by way of reimbursement.
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§ 1001. Congressional statement of purpose

(a) The Congress hereby finds and declares that drug and alcohol abuse diminishes the strength and vitality of the people of our Nation; that an increasing number of substances, both legal and illegal, are being abused by increasing numbers of individuals; that abuse of any substance is complex human behavior which is influenced by many forces, including school, family, church, community, media, and peer groups; and that prevention and early intervention in such behavior require cooperation and coordination among all of these elements in strategies designed to respond to carefully defined problems.

(b) It is the purpose of this chapter to encourage the development of new and improved curricula on the problems of drug abuse; to demonstrate the use of such curricula in model educational programs and to evaluate the effectiveness thereof; to disseminate curricular materials and significant information for use in educational programs throughout the Nation; to provide training programs for teachers, counselors, law enforcement officials, and other public service and community leaders; and to offer community education programs for parents and others, on drug abuse problems.

(c) It is further the purpose of this chapter to provide leadership to schools and other institutions in the community by supporting projects to identify, evaluate, demonstrate, and disseminate effective strategies for prevention and early intervention and to provide training and technical assistance to schools and other segments of the community in adapting such strategies to identified local needs.

(Pub. L. 91-527, § 2, Dec. 3, 1970, 84 Stat. 1385; Pub. L. 93-422, § 2(b), Sept. 21, 1974, 88 Stat. 1154.)

Amendments

1974—Subsec. (a). Pub. L. 93-422 substituted findings relating to the effects of drug and alcohol abuse for findings relating to the effects of drug abuse.

Subsec. (c). Pub. L. 93-422 added subsec. (c).

Short Title of 1974 Amendment

Section 1 of Pub. L. 93-422 provided: "That this Act [amending sections 1001 to 1004, and 1007 of this title and amending provisions set out as a note under this section] may be cited as the 'Alcohol and Drug Abuse Education Act Amendments of 1974'."

SHORT TITLE

Section 1 of Pub. L. 91-527 as amended by section 2(a) of Pub. L. 93-422 provided that: "This Act [enacting this chapter] may be cited as the 'Alcohol and Drug Abuse Education Act'."

§ 1002. Alcohol and drug abuse education projects

(a) Authorization to make grants and contracts

The Commissioner of Education shall carry out a program of making grants to, and contracts with institutions of higher education, State and local educational agencies, and public and private education or community agencies, institutions, and organizations to support and evaluate demonstration projects, to encourage the establishment of such projects throughout the Nation, to train educational and community personnel, and to provide technical assistance in program development. In carrying out such program, the Commissioner of Education shall give priority to school based programs and projects.

(b) Availability of appropriations; bilingual and other permissible activities

Funds appropriated for grants and contracts under this chapter shall be available for activities, including bilingual activities, such as—

(1) projects for the development, testing, evaluation, and dissemination of exemplary materials for use in elementary, secondary, adult, and community education programs, and for training in the selection and use of such materials;

(2) comprehensive demonstration programs which focus on the causes of drug and alcohol abuse rather than on the symptoms; which include both schools and the communities within which the schools are located; which emphasizes the affective as well as the cognitive approach; which reflect the specialized needs of communities; and which include, in planning and development, school personnel, the target population, community representation, and parents;

(3) creative primary prevention and early intervention programs in schools, utilizing an interdisciplinary "school team" approach, developing in educational personnel and students skills in planning and conducting comprehensive prevention programs which include such activities as training drug and alcohol education specialists and group leaders, peer group and individual counseling, and student involvement in intellectual, cultural, and social alternatives to drug and alcohol abuse;

(4) preservice and inservice training programs on drug and alcohol abuse prevention for teachers, counselors, and other educational personnel, law enforcement officials, and other public service and community leaders and personnel;

(5) community education programs on drug and alcohol abuse, especially for parents and others in the community;

(6) programs or projects to recruit, train, organize, and employ professionals and other persons, including former drug and alcohol abusers and former drug- and alcohol-dependent persons, to organize and participate in programs of public education in drug and alcohol abuse; and

(7) projects for the dissemination of valid and effective school and community drug and alcohol abuse educational programs.

(c) Availability of funds for expenses of State educational agencies in assisting local educational agencies in planning, development and implementation of programs

In addition to the purposes described in subsection (b) of this section, funds in an amount not to exceed 10 per centum of the sums appropriated to carry out this chapter may be made available for the payment of reasonable and necessary expenses of State educational agencies for assisting local educational agencies in the planning, development, and implementation of drug and alcohol abuse education programs, including such projects as—

(1) inservice training of education personnel,

(2) technical assistance to local school districts,

(3) creative leadership in programing for indigenous minorities, and

(4) training of peer counselors.

(d) Applications for assistance; requirements; approval and amendment of applications

(1) Financial assistance under this section may be made only upon application at such time or times, in such manner, and containing or accompanied by such information as the Commissioner deems necessary, and only if such application—

(A) provides that activities and services for which assistance under this chapter is sought will be administered by or under the supervision of the applicant;

(B) provides for carrying out one or more projects or programs eligible for assistance under subsections (b) and (c) of this section and provides for such methods of administration as are necessary for the proper and efficient operation of such projects or programs;

(C) sets forth policies and procedures which assure that Federal funds made available under this section for any fiscal year will be so used as to supplement and, to the extent practical, increase the level of funds that would, in the absence of such Federal funds, be made available by the applicant for the purposes described in subsections (b) and (c) of this section, and in no case supplant such funds; and

(D) provides for making such reports, in such form and containing such information, as the Commissioner may reasonably require, and for keeping such records and affording such access thereto as the Commissioner may find necessary to assure to correctness and verification of such reports.

(2) An application from a local education agency for financial assistance under this section may be approved by the Commissioner only after the applicant has submitted the application to the State educational agency. The State educational agency shall, not more than thirty days after the date of receipt of the application, submit to the Secretary in writing its comments on the application. A copy of such comments shall be submitted at the same time to the applicant.

(3) Amendments of applications shall, except as the Commissioner may otherwise provide by or pursuant to regulation, be subject to the requirements set forth in subsections (d)(1) and (d)(2) of this section.

(e) Evaluation of programs; reports to Congress

(1) The Commissioner may use funds in an amount not exceeding 1 per centum of the funds appropriated to carry out this section for a fiscal year for independent analysis and evaluation of the effectiveness of the drug and alcohol abuse education programs assisted under this section.

(2) The Commissioner shall, not later than March 31 of each calendar year, submit an evaluation report to the House and Senate Committees on Appropriations, the House Committee on Education and Labor, and the Senate Committee on Human Resources. Such report shall—

(A) contain the agency's statement of specific and detailed objectives for the program or programs assisted under the provisions of this chapter, and relate these objectives to those in the chapter,

(B) include statements of the agency's conclusions as to effectiveness of the program or programs in meeting the stated objectives, measured through the end of the preceding fiscal year,

(C) make recommendations with respect to any changes or additional legislative action deemed necessary or desirable in carrying out the program or programs,

(D) contain a listing identifying the principal analyses and studies supporting the major conclusions and recommendations, and

(E) contain the agency's annual evaluation plan for the program or programs through the ensuing fiscal year for which the budget was transmitted to Congress by the President, in accordance with section 11(a) of title 31.

(f) Authorization of appropriations

There are authorized to be appropriated to carry out the purposes of this section $26,000,000 for the fiscal year ending June 30, 1975, $30,000,000 for the fiscal year ending June 30, 1976, and $34,000,000 for the fiscal year ending June 30, 1977. Not less than 60 per centum of the amount appropriated for a fiscal year under this section shall be used for drug and alcohol abuse education programs and projects in elementary and secondary schools.

(Pub. L. 91-527, § 3, Dec. 3, 1970, 84 Stat. 1386; Pub. L. 93-422, § 2(c), Sept. 21, 1974, 88 Stat. 1155; S. Res. 4, Feb. 4, 1977.)

CODIFICATION

"This chapter", referred to in subsec. (d)(1)(A), was, in the original, "this title", which has been translated as "this chapter" as the probable intent of Congress.

AMENDMENTS

1974—Subsec. (a). Pub. L. 93-422 substituted "Commissioner of Education" for "Secretary" and extended the functions of the Commissioner to make grants and contracts to encourage the establishment of projects throughout the Nation, to train educational and community personnel, and to provide technical assistance in program development, and added provision that the Commissioner give priority to school based programs and projects.

Subsec. (b). Pub. L. 93-422 extended the use of funds appropriated for bilingual activities and certain alcohol abuse demonstration and prevention programs.

Subsec. (c). Pub. L. 93-422 substituted "not to exceed 10 per centum" for "not to exceed 5 per centum" and enumerated in pars. (1)-(4), the type of projects for which the funds may be made available.

Subsec. (d). Pub. L. 93-422 in par. (1), substituted "Commissioner" for "Secretary" in three places, added reference to subsec. (c) of this section in subpars. (B), (C), and (D), in par. (2), substituted provisions prescribing procedure for the submission and approval of applications from local educational agencies for provisions that the Secretary may approve such applications only if state educational agency has been notified of the application and been given opportunity to offer recommendations, and in par. (3), substituted "Commissioner" for "Secretary" and added provision that amendment of applications would be subject to par. (2) of this subsection.

Subsec. (e). Pub. L. 93-422 added subsec. (e). Former subsec. (e) redesignated (f).

Subsec. (f). Pub. L. 93-422 redesignated former subsec. (e) as (f), and in subsec. (f) as so redesignated, substituted authorization of appropriations for the fiscal years 1975, 1976, and 1977, for such authorization of appropriations for fiscal years 1971, 1972, and 1973.

CHANGE OF NAME

The Committee on Labor and Public Welfare of the Senate was abolished and replaced by the Committee on Human Resources of the Senate, effective Feb. 11, 1977. See Rule XXV of the Standing Rules of the Senate, as amended by Senate Resolution 4 (popularly cited as the "Committee System Reorganization Amendments of 1977"), approved Feb. 4, 1977.

§ 1003. Recordkeeping requirements; access to and inspection of records

(a) Each recipient of Federal assistance under this chapter, pursuant to grants, subgrants, contracts, subcontracts, loans, or other arrangements entered into other than by formal advertising, and which are otherwise authorized by this chapter, shall keep such records as the Commissioner shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such assistance, the total cost of the project or undertaking in connection with which such assistance is given or used, the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(b) The Secretary and the Comptroller General of the United States or any of their duly authorized representatives, shall, until the expiration of three years after completion of the project or undertaking referred to in subsection (a) of this section, have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients which in the opinion of the Secretary or the Comptroller General may be related or pertinent to the grants, subgrants, contracts, subcontracts, loans, or other arrangements referred to in subsection (a) of this section.

(Pub. L. 91-527, § 4, Dec. 3, 1970, 84 Stat. 1387; Pub. L. 93-422, § 2(d), Sept. 21, 1974, 88 Stat. 1157.)

AMENDMENTS

1974—Pub. L. 93-422 substituted provisions relating to recordkeeping by recipients of financial assistance and for inspection of the records by the Secretary and

the Comptroller General of the United States, for provisions relating to authorization of appropriations, authority of the Secretary to make grants and contracts to community education projects, and the type and extent of programs.

§ 1004. Technical assistance

The Secretary and the Attorney General (on matters of law enforcement) shall, when requested, render technical assistance to local educational agencies, public and private nonprofit organizations, and institutions of higher education in the development and implementation of programs of drug and alcohol abuse education. Such technical assistance may, among other activities, include making available to such agencies or institutions information regarding effective methods of coping with problems of drug and alcohol abuse, and making available to such agencies or institutions personnel of the Department of Health, Education, and Welfare and the Department of Justice, or other persons qualified to advise and assist in coping with such problems or carrying out a drug and alcohol abuse education program.

(Pub. L. 91-527, § 5, Dec. 3, 1970, 84 Stat. 1388; Pub. L. 93-422, § 2(e), Sept. 21, 1974, 88 Stat. 1157.)

AMENDMENTS

1974—Pub. L. 93-422 substituted "drug and alcohol abuse" for "drug abuse" in three places.

§ 1005. Payments in installments and in advance or by way of reimbursement

Payments under this chapter may be made in installments and in advance or by way of reimbursement, with necessary adjustments on account of overpayments or underpayments.

(Pub. L. 91-527, § 6, Dec. 3, 1970, 84 Stat. 1388.)

§ 1006. Administration; utilization of services and facilities of Federal agencies and public or private agencies or institutions

In administering the provisions of this chapter, the Secretary is authorized to utilize the services and facilities of any agency of the Federal Government and of any other public or private agency or institution in accordance with appropriate agreements, and to pay for such services either in advance or by way of reimbursement, as may be agreed upon.

(Pub. L. 91-527, § 7, Dec. 3, 1970, 84 Stat. 1388.)

§ 1007. Definitions

As used in this chapter—

(a) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(b) The term "Commissioner" means the Commissioner of Education.

(c) The term "State" includes, in addition to the several States of the Union, the Commonwealth of Puerto Rico, the District of Columbia, Guam, American Samoa, the Virgin Islands, and the Trust Territory of the Pacific Islands.

(Pub. L. 91-527, § 8, Dec. 3, 1970, 84 Stat. 1388; Pub. L. 93-422, § 2(f), Sept. 21, 1974, 88 Stat. 1157.)

AMENDMENTS

1974—Subsec. (b). Pub. L. 93-422 added subsec. (b). Former subsec. (b) redesignated (c).

Subsec. (c). Pub. L. 93-422 redesignated former subsec. (b) as (c).

CHAPTER 15—EGG PRODUCTS INSPECTION

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1056. Separability of provisions.

§ 1031. Congressional statement of findings

Eggs and egg products are an important source of the Nation's total supply of food, and are used in food in various forms. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential, in the public interest, that the health and welfare of consumers be protected by the adoption of measures prescribed herein for assuring that eggs and egg products distributed to them and used in products consumed by them are wholesome, otherwise not adulterated, and properly labeled and packaged. Lack of effective regulation for the handling or disposition of unwholesome, otherwise adulterated, or improperly labeled or packaged egg products and certain qualities of eggs is injurious to the public welfare and destroys markets for wholesome, not adulterated, and properly labeled and packaged eggs and egg products and results in sundry losses to producers and processors, as well as injury to consumers. Unwholesome, otherwise adulterated, or improperly labeled or packaged products can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged products, to the detriment of consumers and the public generally. It is hereby found that all egg products and the qualities of eggs which are regulated under this chapter are either in interstate or foreign commerce, or substantially affect such commerce, and that regulation by the Secretary of Agriculture and the Secretary of Health, Education, and Welfare, and cooperation by the States and other jurisdictions, as contemplated by this chapter, are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

(Pub. L. 91-597, § 2, Dec. 29, 1970, 84 Stat. 1620.)

References in Text

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under this section and Tables volume.

Effective Date

Section 29 of Pub. L. 91-597 provided that: "The provisions of this Act [enacting this chapter, amending sections 633 and 636 of Title 15, Commerce and Trade, and enacting provisions set out as notes under this section] with respect to egg products shall take effect six months after enactment [Dec. 29, 1970]. Otherwise, this Act shall take effect eighteen months after enactment."

Short Title

Section 1 of Pub. L. 91-597 provided: "That this Act [which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set as notes under this section] may be cited as the 'Egg Products Inspection Act'."

§ 1032. Congressional declaration of policy

It is hereby declared to be the policy of the Congress to provide for the inspection of certain egg products, restrictions upon the disposition of certain qualities of eggs, and uniformity of standards for eggs, and otherwise regulate the processing and distribution of eggs and egg products as hereinafter prescribed to prevent the movement or sale for human food, of eggs and egg products which are adulterated or misbranded or otherwise in violation of this chapter.

(Pub. L. 91-597, § 3, Dec. 29, 1970, 84 Stat. 1621.)

References in Text

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

§ 1033. Definitions

For purposes of this chapter—

(a) The term "adulterated" applies to any egg or egg product under one or more of the following circumstances—

(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;

(B) if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title;

(C) if it bears or contains any food additive which is unsafe within the meaning of section 348 of this title;

(D) if it bears or contains any color additive which is unsafe within the meaning of section 376 of this title: *Provided*, That an article which is not otherwise deemed adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive, in or on such article, is prohibited by regulations of the Secretary in official plants;

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for human food;

(4) if it has been prepared, packaged, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) if it is an egg which has been subjected to incubation or the product of any egg which has been subjected to incubation;

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title; or

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(b) The term "capable of use as human food" shall apply to any egg or egg product, unless it is denatured, or otherwise identified, as required by regulations prescribed by the Secretary to deter its use as human food.

(c) The term "commerce" means interstate, foreign, or intrastate commerce.

(d) The term "container" or "package" includes any box, can, tin, plastic, or other receptacle, wrapper, or cover.

(1) The term "immediate container" means any consumer package; or any other container in which egg products, not consumer packaged, are packed.

(2) The term "shipping container" means any container used in packaging a product packed in an immediate container.

(e) The term "egg handler" means any person who engages in any business in commerce which involves buying or selling any eggs (as a poultry producer or otherwise), or processing any egg products, or otherwise using any eggs in the preparation of human food.

(f) The term "egg product" means any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as he may prescribe to assure that the egg ingredients are not adulterated and such products are not represented as egg products.

(g) The term "egg" means the shell egg of the domesticated chicken, turkey, duck, goose, or guinaea.

(1) The term "check" means an egg that has a broken shell or crack in the shell but has its shell membranes intact and contents not leaking.

(2) The term "clean and sound shell egg" means any egg whose shell is free of adhering dirt or foreign material and is not cracked or broken.

(3) The term "dirty egg" means an egg that has a shell that is unbroken and has adhering dirt or foreign material.

(4) The term "incubator reject" means an egg that has been subjected to incubation and has been removed from incubation during the hatching operations as infertile or otherwise unhatchable.

(5) The term "inedible" means eggs of the following descriptions: black rots, yellow rots, white rots, mixed rots (addled eggs), sour eggs, eggs with green whites, eggs with stuck yolks, moldy eggs, musty eggs, eggs showing blood rings, and eggs containing embryo chicks (at or beyond the blood ring stage.)

(6) The term "leaker" means an egg that has a crack or break in the shell and shell membranes to the extent that the egg contents are exposed or are exuding or free to exude through the shell.

(7) The term "loss" means an egg that is unfit for human food because it is smashed or broken so that its contents are leaking; or overheated, frozen, or contaminated; or an incubator reject; or because it contains a bloody white, large meat spots, a large quantity of blood, or other foreign material.

(8) The term "restricted egg" means any check, dirty egg, incubator reject, inedible, leaker, or loss.

(h) The term "Fair Packaging and Labeling Act" [15 U.S.C. 1451 et seq.] means the Act so entitled, approved November 3, 1966, (80 Stat. 1296), and Acts amendatory thereof or supplementary thereto.

(i) The term "Federal Food, Drug, and Cosmetic Act" [21 U.S.C. 301 et seq.] means the Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

(j) The term "inspection" means the application of such inspection methods and techniques as are deemed necessary by the responsible Secretary to carry out the provisions of this chapter.

(k) The term "inspector" means:

(1) any employee or official of the United States Government authorized to inspect eggs or egg products under the authority of this chapter; or

(2) any employee or official of the government of any State or local jurisdiction authorized by the Secretary to inspect eggs or egg products under the authority of this chapter, under an agreement entered into between the Secretary and the appropriate State or other agency.

(l) The term "misbranded" shall apply to egg products which are not labeled and packaged in accordance with the requirements prescribed by regulations of the Secretary under section 1036 of this title.

(m) The term "official certificate" means any certificate prescribed by regulations of the Secretary for issuance by an inspector or other person performing official functions under this chapter.

(n) The term "official device" means any device prescribed or authorized by the Secretary for use in applying any official mark.

(o) The term "official inspection legend" means any symbol prescribed by regulations of the Secretary showing that egg products were inspected in accordance with this chapter.

(p) The term "official mark" means the official inspection legend or any other symbol prescribed by regulations of the Secretary to identify the status of any article under this chapter.

(q) The term "official plant" means any plant, as determined by the Secretary, at which inspection of the processing of egg products is maintained by the Department of Agriculture under the authority of this chapter.

(r) The term "official standards" means the standards of quality, grades, and weight classes for eggs, in effect upon the effective date of this chapter, or as thereafter amended, under the Agricultural Marketing Act of 1946 (60 Stat. 1087, as amended; 7 U.S.C. 1621 et seq.).

(s) The term "pasteurize" means the subjecting of each particle of egg products to heat or other treatments to destroy harmful viable micro-organisms by such processes as may be prescribed by regulations of the Secretary.

(t) The term "person" means any individual, partnership, corporation, association, or other business unit.

(u) The terms "pesticide chemical," "food additive," "color additive," and "raw agricultural commodity" shall have the same meaning for purposes of this chapter as under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(v) The term "plant" means any place of business where egg products are processed.

(w) The term "processing" means manufacturing egg products, including breaking eggs or filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing, drying, or packaging egg products.

(x) The term "Secretary" means the Secretary of Agriculture or his delegate.

(y) The term "State" means any State of the United States, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, and the District of Columbia.

(z) The term "United States" means the States.

(Pub. L. 91-597, § 4, Dec. 29, 1970, 84 Stat. 1621.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

The Fair Packaging and Labeling Act, referred to in subsec. (h), is Pub. L. 89-755, Nov. 3, 1966, 80 Stat. 1296, as amended, which is classified generally to chapter 39 (§ 1451 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note under section 1451 of Title 15 and Tables volume.

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (i) and (u), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables volume.

The effective date of this chapter, referred to in subsec. (r), means the effective date of Pub. L. 91-597. For such effective date, see Effective Date note set out under section 1031 of this title.

The Agricultural Marketing Act of 1946, referred to in subsec. (r), is title II of act Aug. 14, 1946, ch. 966, 60 Stat 1087, as amended, which is classified generally to chapter 38 (§ 1621 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note Under section 1621 of Title 7 and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1041 of this title; title 15 sections 2052, 2602.

§ 1034. Inspection of egg products

(a) Processing operations and establishments subject to coverage; rules and regulations

For the purpose of preventing the entry into or flow or movement in commerce of, or the burdening of commerce by, any egg product which is capable of use as human food and is misbranded or adulterated, the Secretary shall, whenever processing operations are being conducted, cause continuous inspection to be made, in accordance with the regulations promulgated under this chapter, of the processing of egg products, in each plant processing egg products for commerce, unless exempted under section 1044 of this title. Without restricting the application of the preceding sentence to other kinds of establishments within its provisions, any

food manufacturing establishment, institution, or restaurant which uses any eggs that do not meet the requirements of section 1044(a)(1) of this title in the preparation of any articles for human food shall be deemed to be a plant processing egg products, with respect to such operations.

(b) Authority of Secretary to retain, segregate, and reinspect eggs and egg products

The Secretary, at any time, shall cause such retention, segregation, and reinspection as he deems necessary of eggs and egg products capable of use as human food in each official plant.

(c) Condemnation of adulterated products; destruction or reprocessing; procedure upon appeal from determination of adulteration

Eggs and egg products found to be adulterated at official plants shall be condemned and, if no appeal be taken from such determination of condemnation, such articles shall be destroyed for human food purposes under the supervision of an inspector: *Provided,* That articles which may by reprocessing be made not adulterated need not be condemned and destroyed if so reprocessed under the supervision of an inspector and thereafter found to be not adulterated. If an appeal be taken from such determination, the eggs or egg products shall be appropriately marked and segregated pending completion of an appeal inspection, which appeal shall be at the cost of the appellant if the Secretary determines that the appeal is frivolous. If the determination of condemnation is sustained, the eggs or egg products shall be destroyed for human food purposes under the supervision of an inspector.

(d) Inspection of business premises, facilities, inventory, operations, and records of egg handlers; inspection of records and inventory of others required to keep records; authority of Secretary of Health, Education, and Welfare to inspect food manufacturing establishments, institutions, and restaurants; access to places of business

The Secretary shall cause such other inspections to be made of the business premises, facilities, inventory, operations, and records of egg handlers, and the records and inventory of other persons required to keep records under section 1040 of this title, as he deems appropriate (and in the case of shell egg packers, packing eggs for the ultimate consumer, at least once each calendar quarter) to assure that only eggs fit for human food are used for such purpose, and otherwise to assure compliance by egg handlers and other persons with the requirements of section 1037 of this title, except that the Secretary of Health, Education, and Welfare shall cause such inspections to be made as he deems appropriate to assure compliance with such requirements at food manufacturing establishments, institutions, and restaurants, other than plants processing egg products. Representatives of said Secretaries shall be afforded access to all such places of business for purposes of making the inspections provided for in this chapter.

(Pub. L. 91-597, § 5, Dec. 29, 1970, 84 Stat. 1624.)

REFERENCES IN TEXT

This chapter, referred to in subsecs. (a) and (d), was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1043, 1052 of this title.

§ 1035. Sanitary operating practices in official plants; required premises, facilities, and equipment; refusal by Secretary to inspect nonconforming plants

(a) Each official plant shall be operated in accordance with such sanitary practices and shall have such premises, facilities, and equipment as are required by regulations promulgated by the Secretary to effectuate the purposes of this chapter, including requirements for segregation and disposition of restricted eggs.

(b) The Secretary shall refuse to render inspection to any plant whose premises, facilities, or equipment, or the operation thereof, fail to meet the requirements of this section.

(Pub. L. 91-597, § 6, Dec. 29, 1970, 84 Stat. 1625.)

REFERENCES IN TEXT

This chapter, referred to in subsec. (a), was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1037 of this title.

§ 1036. Pasteurization and labeling of egg products at official plants; contents of labels; false or misleading or use of nonapproved labeling or containers; determination by Secretary; procedure; appeal from determination

(a) Egg products inspected at any official plant under the authority of this chapter and found to be not adulterated shall be pasteurized before they leave the official plant, except as otherwise permitted by regulations of the Secretary, and shall at the time they leave the official plant, bear in distinctly legible form on their shipping containers or immediate containers, or both, when required by regulations of the Secretary, the official inspection legend and official plant number, of the plant where the products were processed, and such other information as the Secretary may require by regulations to describe the products adequately and to assure that they will not have false or misleading labeling.

(b) No labeling or container shall be used for egg products at official plants if it is false or misleading or has not been approved as required by the regulations of the Secretary. If the Secretary has reason to believe that any labeling or the size or form of any container in use or proposed for use with respect to egg products at any official plant is false or misleading in any particular, he may direct that such use be withheld unless the labeling or container is modified in such manner as he may

prescribe so that it will not be false or misleading. If the person using or proposing to use the labeling or container does not accept the determination of the Secretary, such person may request a hearing, but the use of the labeling or container shall, if the Secretary so directs, be withheld pending hearing and final determination by the Secretary. Any such determination by the Secretary shall be conclusive unless, within thirty days after receipt of notice of such final determination, the person adversely affected thereby appeals to the United States court of appeals for the circuit in which such person has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit. The provisions of section 194 of title 7, shall be applicable to appeals taken under this section.

(Pub. L. 91-597, § 7, Dec. 29, 1970, 84 Stat. 1625.)

REFERENCES IN TEXT

This chapter, referred to in subsec. (a), was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1033, 1037 of this title.

§ 1037. Prohibited acts

(a)(1) No person shall buy, sell, or transport, or offer to buy or sell, or offer or receive for transportation, in any business in commerce any restricted eggs, capable of use as human food, except as authorized by regulations of the Secretary under such conditions as he may prescribe to assure that only eggs fit for human food are used for such purpose.

(2) No egg handler shall possess with intent to use, or use, any restricted eggs in the preparation of human food for commerce except that such eggs may be so possessed and used when authorized by regulations of the Secretary under such conditions as he may prescribe to assure that only eggs fit for human food are used for such purpose.

(b)(1) No person shall process any egg products for commerce at any plant except in compliance with the requirements of this chapter.

(2) No person shall buy, sell, or transport, or offer to buy or sell, or offer or receive for transportation, in commerce any egg products required to be inspected under this chapter unless they have been so inspected and are labeled and packaged in accordance with the requirements of section 1036 of this title.

(3) No operator of any official plant shall fail to comply with any requirements of section 1035(a) of this title or the regulations thereunder.

(4) No operator of any official plant shall allow any egg products to be moved from such plant if they are adulterated or misbranded and capable of use as human food.

(c) No person shall violate any provision of section 1039, 1040 or 1046 of this title.

(d) No person shall—

(1) manufacture, cast, print, lithograph, or otherwise make any device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, or any form of official certificate or simulation thereof, except as authorized by the Secretary;

(2) forge or alter any official device, mark, or certificate;

(3) without authorization from the Secretary, use any official device, mark, or certificate, or simulation thereof, or detach, deface, or destroy any official device or mark; or use any labeling or container ordered to be withheld from use under section 1036 of this title after final judicial affirmance of such order or expiration of the time for appeal if no appeal is taken under said section;

(4) contrary to the regulations prescribed by the Secretary, fail to use, or to detach, deface, or destroy any official device, mark, or certificate;

(5) knowingly possess, without promptly notifying the Secretary or his representative, any official device or any counterfeit, simulated, forged, or improperly altered official certificate or any device or label, or any eggs or egg products bearing any counterfeit, simulated, forged, or improperly altered official mark;

(6) knowingly make any false statement in any shipper's certificate or other nonofficial or official certificate provided for in the regulations prescribed by the Secretary;

(7) knowingly represent that any article has been inspected or exempted, under this chapter, when, in fact, it has, respectively, not been so inspected or exempted; and

(8) refuse access, at any reasonable time, to any representative of the Secretary of Agriculture or the Secretary of Health, Education, and Welfare, to any plant or other place of business subject to inspection under any provisions of this chapter.

(e) No person, while an official or employee of the United States Government or any State or local governmental agency, or thereafter, shall use to his own advantage, or reveal other than to the authorized representatives of the United States Government or any State or other government in their official capacity, or as ordered by a court in a judicial proceeding, any information acquired under the authority of this chapter concerning any matter which is entitled to protection as a trade secret.

(Pub. L. 91-597, § 8, Dec. 29, 1970, 84 Stat. 1626.)

REFERENCES IN TEXT

This chapter, referred to in subsecs. (b)(1), (2), (d)(7), (8), and (e), was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter and amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1034, 1041 of this title.

§ 1038. Cooperation with appropriate State and other governmental agencies; utilization of employees; reimbursement

The Secretary shall, whenever he determines that it would effectuate the purposes of this chapter, cooperate with appropriate State and other governmental agencies, in carrying out any provisions of this chapter. In carrying out the provisions of this chapter, the Secretary may conduct such examinations, investigations, and inspections as he determines practicable through any officer or employee of any such agency commissioned by him for such purpose. The Secretary shall reimburse the States and other agencies for the costs incurred by them in such cooperative programs.

(Pub. L. 91-597, § 9, Dec. 29, 1970, 84 Stat. 1627.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

§ 1039. Egg and egg products not intended for use as human food; inspection; denaturing or otherwise identifying

Inspection shall not be provided under this chapter at any plant for the processing of any egg products which are not intended for use as human food, but such articles, prior to their offer for sale or transportation in commerce, shall be denatured or otherwise identified as prescribed by regulations of the Secretary to deter their use for human food. No person shall buy, sell, or transport or offer to buy or sell, or offer or receive for transportation, in commerce, any restricted eggs or egg products which are not intended for use as human food unless they are denatured or otherwise identified as required by the regulations of the Secretary.

(Pub. L. 91-597, § 10, Dec. 29, 1970, 84 Stat. 1627.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1037 of this title.

§ 1040. Recordkeeping requirements; persons required to maintain records; scope of disclosure; access to records

For the purpose of enforcing the provisions of this chapter and the regulations promulgated thereunder, all persons engaged in the business of transporting, shipping, or receiving any eggs or egg products in commerce or holding such articles so received, and all egg handlers, shall maintain such records showing, for such time and in such form and manner, as the Secretary of Agriculture or the Secretary of Health, Education, and Welfare may prescribe, to the extent that they are concerned therewith, the receipt, delivery, sale, movement, and disposition of all eggs and egg products handled by them, and shall, upon the request of a duly authorized representative of either of said Secretaries, permit him at reasonable times to have access to and to copy all such records.

(Pub. L. 91-597, § 11, Dec. 29, 1970, 84 Stat. 1627.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1034, 1037, 1041, 1052 of this title.

§ 1041. Penalties; scope of liability

(a) Any person who commits any offense prohibited by section 1037 of this title shall upon conviction be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine, but if such violation involves intent to defraud, or any distribution or attempted distribution of any article that is known to be adulterated (except as defined in section 1033(a)(8) of this title), such person shall be subject to imprisonment for not more than three years or a fine of not more than $10,000, or both. When construing or enforcing the provisions of section 1037 of this title, the act, omission, or failure of any person acting for or employed by any individual, partnership, corporation, or association within the scope of his employment or office shall in every case be deemed the act, omission, or failure of such individual, partnership, corporation, or association, as well as of such person.

(b) No carrier or warehouseman shall be subject to the penalties of this chapter, other than the penalties for violation of section 1040 of this title or subsection (c) of this section, by reason of his receipt, carriage, holding, or delivery, in the usual course of business, as a carrier or warehouseman of eggs or egg products owned by another person unless the carrier or warehouseman has knowledge, or is in possession of facts which would cause a reasonable person to believe that such eggs or egg products were not eligible for transportation under, or were otherwise in violation of, this chapter, or unless the carrier or warehouseman refuses to furnish on request of a representative of the Secretary the name and address of the person from whom he received such eggs or egg products and copies of all documents, if there be any, pertaining to the delivery of the eggs or egg products to, or by, such carrier or warehouseman.

(c) Any person who forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any person while engaged in or on account

of the performance of his official duties under this chapter shall be fined not more than $5,000 or imprisoned not more than three years or both. Whoever, in the commission of any such act, uses a deadly or dangerous weapon, shall be fined not more than $10,000 or imprisoned not more than ten years, or both. Whoever kills any person while engaged in or on account of the performance of his official duties under this chapter shall be punished as provided under sections 1111 and 1112 of title 18.

(Pub. L. 91-597, § 12, Dec. 29, 1970, 84 Stat. 1628.)

REFERENCES IN TEXT

This chapter, referred to in subsecs. (b) and (c), was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

§ 1042. Reporting of violation to United States attorney for institution of criminal proceedings; procedure; presentation of views

Before any violation of this chapter is reported by the Secretary of Agriculture or Secretary of Health, Education, and Welfare to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given reasonable notice of the alleged violation and opportunity to present his views orally or in writing with regard to such contemplated proceeding. Nothing in this chapter shall be construed as requiring the Secretary of Agriculture or Secretary of Health, Education, and Welfare to report for criminal prosecution violations of this chapter whenever he believes that the public interest will be adequately served and compliance with this chapter obtained by a suitable written notice of warning.

(Pub. L. 91-597, § 13, Dec. 29, 1970, 84 Stat. 1628.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

§ 1043. Rules and regulations; administration and enforcement

The Secretary shall promulgate such rules and regulations as he deems necessary to carry out the purposes or provisions of this chapter, and shall be responsible for the administration and enforcement of this chapter except as otherwise provided in section 1034(d) of this title.

(Pub. L. 91-597, § 14, Dec. 29, 1970, 84 Stat. 1629.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

§ 1044. Exemption of certain activities

(a) Regulation for exemptions

The Secretary may, by regulation and under such conditions and procedures as he may prescribe, exempt from specific provisions of this chapter—

(1) the sale, transportation, possession, or use of eggs which contain no more restricted eggs than are allowed by the tolerance in the official standards of United States consumer grades for shell eggs;

(2) the processing of egg products at any plant where the facilities and operating procedures meet such sanitary standards as may be prescribed by the Secretary, and where the eggs received or used in the manufacture of egg products contain no more restricted eggs than are allowed by the official standards of United States consumer grades for shell eggs, and the egg products processed at such plant;

(3) the sale of eggs by any poultry producer from his own flocks directly to a household consumer exclusively for use by such consumer and members of his household and his nonpaying guests and employees, and the transportation, possession, and use of such eggs in accordance with this paragraph;

(4) the processing of egg products by any poultry producer from eggs of his own flocks' production for sale of such products directly to a household consumer exclusively for use by such consumer and members of his household and his nonpaying guests and employees, and the egg products so processed when handled in accordance with this paragraph;

(5) the sale of eggs by shell egg packers on his own premises directly to household consumers for use by such consumer and members of his household and his nonpaying guests and employees, and the transportation, possession, and use of such eggs in accordance with this paragraph;

(6) for such period of time (not to exceed two years) during the initiation of operations under this chapter as the Secretary determines that it is impracticable to provide inspection, the processing of egg products at any class of plants and the egg products processed at such plants; and

(7) the sale of eggs by any egg producer with an annual egg production from a flock of three thousand or less hens.

(b) Plants located in noncontiguous areas of United States

The Secretary shall, by regulation and under such procedures as he may prescribe, exempt any plant located within noncontiguous areas of the United States from specific provisions of this chapter, where, despite good faith efforts by the owner of such plant, such owner has not been able to bring his plant into full compliance with this chapter: *Provided*, That in order to provide at least minimum standards for the protection of the public health, whenever processing operations are being conducted at any such plant, continuous inspection shall be maintained to assure that it is operated in a

sanitary manner. No exemption under this subsection shall be granted for a period extending beyond December 31, 1971.

(c) Suspension or termination of exemptions

The Secretary may immediately suspend or terminate any exemption under subsection (a)(2) or (6) of this section at any time with respect to any person, if the conditions of exemption prescribed by this section or the regulations of the Secretary are not being met. The Secretary may modify or revoke any regulation granting exemption under this chapter whenever he deems such action appropriate to effectuate the purposes of this chapter.

(Pub. L. 91-597, § 15, Dec. 29, 1970, 84 Stat. 1629; Pub. L. 92-67, Aug. 6, 1971, 85 Stat. 173.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

AMENDMENTS

1971—Subsec. (b). Pub. L. 92-67 added subsec. (b). Former subsec. (b) redesignated (c).

Subsec. (c). Pub. L. 92-67 redesignated former subsec. (b) as (c).

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1034 of this title.

§ 1045. Limitation on entry of egg and egg products and other materials into official plants

The Secretary may limit the entry of eggs and egg products and other materials into official plants under such conditions as he may prescribe to assure that allowing the entry of such articles into such plants will be consistent with the purposes of this chapter.

(Pub. L. 91-597, § 16, Dec. 29, 1970, 84 Stat. 1630.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

§ 1046. Imports

(a) Authorization for importation of restricted eggs; prerequisites for importation of egg products; treatment as domestic articles subject to this chapter; marking and labeling exemption for personal consumption

No restricted eggs capable of use as human food shall be imported into the United States except as authorized by regulations of the Secretary. No egg products capable of use as human food shall be imported into the United States unless they were processed under an approved continuous inspection system of the government of the foreign country of origin or subdivision thereof and are labeled and packaged in accordance with, and otherwise comply with the standards of this chapter and regulations issued thereunder applicable to such articles within the United States. All such imported articles shall upon entry into the United States be deemed and treated as domestic articles subject to the other provisions of this chapter: *Provided*, That they shall be labeled as required by such regulations for imported articles: *Provided further*, That nothing in this section shall apply to eggs or egg products purchased outside the United States by any individual for consumption by him and members of his household and his nonpaying guests and employees.

(b) Terms and conditions for destruction

The Secretary may prescribe the terms and conditions for the destruction of all such articles which are imported contrary to this section, unless (1) they are exported by the consignee within the time fixed therefor by the Secretary or (2) in the case of articles which are not in compliance solely because of misbranding, such articles are brought into compliance with this chapter under supervision of authorized representatives of the Secretary.

(c) Payment of storage, cartage, and labor charges by owner or consignee; liens

All charges for storage, cartage, and labor with respect to any article which is imported contrary to this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against such article and any other article thereafter imported under this chapter by or for such owner or consignee.

(d) Prohibition

The importation of any article contrary to this section is prohibited.

(Pub. L. 91-597, § 17, Dec. 29, 1970, 84 Stat. 1630.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1037, 1054 of this title.

§ 1047. Refusal or withdrawal of inspection services; hearing; grounds; person deemed to have responsible connection with business; finality of order of Secretary; judicial review; other provisions for refusal of services unaffected

The Secretary (for such period, or indefinitely, as he deems necessary to effectuate the purposes of this chapter) may refuse to provide or may withdraw inspection service under this chapter with respect to any plant if he determines, after opportunity for a hearing is accorded to the applicant for, or recipient of, such service, that such applicant or recipient is unfit to engage in any business requiring inspection under this chapter because the applicant or recipient or anyone responsibly con-

nected with the applicant or recipient has been convicted in any Federal or State court, within the previous ten years, of (1) any felony or more than one misdemeanor under any law based upon the acquiring, handling, or distributing of adulterated, mislabeled, or deceptively packaged food or fraud in connection with transactions in food, or (2) any felony, involving fraud, bribery, extortion, or any other act or circumstances indicating a lack of the integrity needed for the conduct of operations affecting the public health.

For the purpose of this section, a person shall be deemed to be responsibly connected with the business if he is a partner, officer, director, holder, or owner of 10 per centum or more of its voting stock, or employee in a managerial or executive capacity.

The determination and order of the Secretary with respect thereto under this section shall be final and conclusive unless the affected applicant for, or recipient of, inspection service files application for judicial review within thirty days after the effective date of such order in the United States court of appeals for the circuit in which such applicant or recipient has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit. Judicial review of any such order shall be upon the record upon which the determination and order are based. The provisions of section 194 of title 7 shall be applicable to appeals taken under this section.

This section shall not affect in any way other provisions of this chapter for refusal of inspection services.

(Pub. L. 91-597, § 18, Dec. 29, 1970, 84 Stat. 1630.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1050 of this title.

§ 1048. Administrative detention of violative articles; duration; release; removal of official marks

Whenever any eggs or egg products subject to this chapter, are found by any authorized representative of the Secretary upon any premises and there is reason to believe that they are or have been processed, bought, sold, possessed, used, transported, or offered or received for sale or transportation in violation of this chapter or that they are in any other way in violation of this chapter, or whenever any restricted eggs capable of use as human food are found by such a representative in the possession of any person not authorized to acquire such eggs under the regulations of the Secretary, such articles may be detained by such representative for a reasonable period but not to exceed twenty days, pending action under section 1049 of this title or notification of any Federal, State, or other governmental authorities having jurisdiction over such articles and shall not be moved by any person from the place at which they are located when so detained until released by such representative. All official marks may be required by such representative to be removed from such articles before they are released unless it appears to the satisfaction of the Secretary that the articles are eligible to retain such marks.

(Pub. L. 91-597, § 19, Dec. 29, 1970, 84 Stat. 1631.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1052 of this title.

§ 1049. Seizure and condemnation proceedings; jurisdiction; disposal of condemned articles by destruction or sale; sales restrictions; release under bond of condemned articles; court costs and fees; conformity of proceedings to supplemental rules for admiralty and maritime claims; jury trial; United States as plaintiff; condemnation or seizure under other provisions unaffected

(a) Any eggs or egg products that are or have been processed, bought, sold, possessed, used, transported, or offered or received for sale or transportation, in violation of this chapter, or in any other way are in violation of this chapter; and any restricted eggs, capable of use as human food, in the possession of any person not authorized to acquire such eggs under the regulations of the Secretary shall be liable to be proceeded against and seized and condemned, at any time, on a complaint in any United States district court or other proper court as provided in section 1050 of this title within the jurisdiction of which the articles are found. If the articles are condemned they shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs and fees, and storage and other proper expenses, shall be paid into the Treasury of the United States, but the articles shall not be sold contrary to the provision of this chapter, the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or the Fair Packaging and Labeling Act [15 U.S.C. 1451 et seq.], or the laws of the jurisdiction in which they are sold: *Provided*, That upon the execution and delivery of a good and sufficient bond conditioned that the articles shall not be sold or otherwise disposed of contrary to the provisions of this chapter, the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, or the laws of the jurisdiction in which disposal is made, the court may direct that they be delivered to the owner thereof subject to such supervision by authorized representatives of the Secretary as is necessary to insure compliance with the applicable laws. When a decree of condemnation is entered against the articles and they are released

under bond, or destroyed, court costs and fees, and storage and other proper expenses shall be awarded against the person, if any, intervening as claimant thereof. The proceedings in such cases shall conform, as nearly as may be, to the supplemental rules for certain admiralty and maritime claims, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

(b) The provisions of this section shall in no way derogate from authority for condemnation or seizure conferred by other provisions of this chapter, or other laws.

(Pub. L. 91-597, § 20, Dec. 29, 1970, 84 Stat. 1631.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables volume.

The Fair Packaging and Labeling Act, referred to in subsec. (a), is Pub. L. 89-755, Nov. 3, 1966, 80 Stat. 1296, as amended, which is classified generally to chapter 39 (§ 1451 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note under section 1451 of Title 15 and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1048 of this title.

§ 1050. Jurisdiction of district courts; United States as plaintiff in enforcement and restraining proceedings; subpenas for witnesses

The United States district courts and the District Court of the Virgin Islands are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this chapter, and shall have jurisdiction in all other cases, arising under this chapter, except as provided in section 1047 of this title. All proceedings for the enforcement or to restrain violations of this chapter shall be by and in the name of the United States. Subpenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding.

(Pub. L. 91-597, § 21, Dec. 29, 1970, 84 Stat. 1632.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1049, 1051 of this title.

§ 1051. Other Federal laws applicable for administration and enforcement of chapter; prosecution of inquiries; exercise of jurisdiction

For the efficient administration and enforcement of this chapter, the provisions (including penalties) of sections 46, 48, 49, and 50 of title 15 (except paragraphs (c) through (h) of section 46 and the last paragraph of section 49), and the provisions of section 409(*l*) of title 47, are made applicable to the jurisdiction, powers, and duties of the Secretary in administering and enforcing the provisions of this chapter and to any person with respect to whom such authority is exercised. The Secretary, in person or by such agents as he may designate, may prosecute any inquiry necessary to his duties under this chapter in any part of the United States, and the powers conferred by said sections 49 and 50 of title 15, on the district courts of the United States may be exercised for the purposes of this chapter by any court designated in section 1050 of this title.

(Pub. L. 91-597, § 22, Dec. 29, 1970, 84 Stat. 1632.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

Section 409(*l*) of title 47, referred to in text, was repealed by Pub. L. 91-452, title II, § 242, Oct. 15, 1970, 84 Stat. 930.

§ 1052. State or local regulation

(a) Prohibition against additional or different requirements than Federal requirements relating to premises, facilities, and operations at official plants; authority to impose recordkeeping and related requirements consistent with Federal requirements

Requirements within the scope of this chapter with respect to premises, facilities, and operations of any official plant which are in addition to or different than those made under this chapter may not be imposed by any State or local jurisdiction except that any such jurisdiction may impose recordkeeping and other requirements within the scope of section 1040 of this title, if consistent therewith, with respect to any such plant.

(b) Prohibition against additional or different standards than Federal standards of quality, etc., or requiring labeling to show area of production or origin; authority to require name, address, and license number of processor or packer on containers; prohibition against additional or different requirements than Federal requirements relating to labeling, packaging or ingredients; authority to prevent distribution of violative articles; validity of nonconflicting laws

For eggs which have moved or are moving in interstate or foreign commerce, (1) no State or local jurisdiction may require the use of stan-

dards of quality, condition, weight, quantity, or grade which are in addition to or different from the official Federal standards, and (2) no State or local jurisdiction other than those in noncontiguous areas of the United States may require labeling to show the State or other geographical area of production or origin: *Provided, however,* That this shall not preclude a State from requiring that the name, address, and license number of the person processing or packaging eggs, be shown on each container. Labeling, packaging, or ingredient requirements, in addition to or different than those made under this chapter, the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and the Fair Packaging and Labeling Act [15 U.S.C. 1451 et seq.], may not be imposed by any State or local jurisdiction, with respect to egg products processed at any official plant in accordance with the requirements under this chapter and such Acts. However, any State or local jurisdiction may exercise jurisdiction with respect to eggs and egg products for the purpose of preventing the distribution for human food purposes of any such articles which are outside of such a plant and are in violation of any of said Federal Acts or any State or local law consistent therewith. Otherwise the provisions of this chapter shall not invalidate any law or other provisions of any State or other jurisdiction in the absence of a conflict with this chapter.

(c) Applicability of other Federal laws and authority of other Federal officials relating to eggs, egg products, or other food products unaffected; authority of Secretary of Agriculture to regulate official plants processing egg products

The provisions of this chapter shall not affect the applicability of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or the Fair Packaging and Labeling Act [15 U.S.C. 1451 et seq.] or other Federal laws to eggs, egg products, or other food products or diminish any authority conferred on the Secretary of Health, Education, and Welfare or other Federal officials by such other laws, except that the Secretary of Agriculture shall have exclusive jurisdiction to regulate official plants processing egg products and operations thereof as to all matters within the scope of this chapter.

(d) Detainer authority

The detainer authority conferred on representatives of the Secretary of Agriculture by section 1048 of this title shall also apply to any authorized representative of the Secretary of Health, Education, and Welfare for the purposes of section 1034(d) of this title, with respect to any eggs or egg products that are outside any plant processing egg products.

(Pub. L. 91-597, § 23, Dec. 29, 1970, 84 Stat. 1632.)

REFERENCES IN TEXT

This chapter, referred to in subsecs. (a), (b), and (c), was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (b) and (c), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables volume.

The Fair Packaging and Labeling Act, referred to in subsecs. (b) and (c), is Pub. L. 89-755, Nov. 3, 1966, 80 Stat. 1296, which is classified generally to chapter 39 (§ 1451 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note under section 1451 of Title 15 and Tables volume.

§ 1053. Inspection and administration costs; overtime and holiday work costs; availability of funds without fiscal year limitation; holiday defined

(a) The cost of inspection rendered under the requirements of this chapter, and other costs of administration of this chapter, shall be borne by the United States, except that the cost of overtime and holiday work performed in official plants subject to the provisions of this chapter at such rates as the Secretary may determine shall be borne by such official plants. Sums received by the Secretary from official plants under this section shall be available without fiscal year limitation to carry out the purposes of this chapter.

(b) The term "holiday" for the purposes of assessment or reimbursement of the cost of inspection performed under this chapter, the Wholesome Poultry Products Act [21 U.S.C. 467a et seq.] and the Wholesome Meat Act [21 U.S.C. 601 et seq.] shall mean the legal public holidays specified by the Congress in section 6103(a) of title 5.

(Pub. L. 91-597, § 24, Dec. 29, 1970, 84 Stat. 1633.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

The Wholesome Poultry Products Act, referred to in subsec. (b), is Pub. L. 90-492, Aug. 18, 1968, 82 Stat. 791, as amended, which enacted sections 467a to 467f and 470 of this title, amended sections 451 to 461, 463 to 465, and 467 of this title, and enacted provisions set out as notes under section 451 of this title. For complete classification of this Act to the Code, see Short Title of 1968 Amendment note set out under section 451 of this title and Tables volume.

The Wholesome Meat Act, referred to in subsec. (b), is Pub. L. 90-201, Dec. 15, 1967, 81 Stat. 584, as amended, which enacted sections 601, 602, 624, 641 to 645, 661, 671 to 680, and 691 of this title, amended sections 603 to 623 of this title, repealed section 96 of this title and section 1306(b) of Title 19, Customs Duties, and enacted provisions set out as notes under this section. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables volume.

§ 1054. Annual report

Not later than March 1 of each year following December 29, 1970, the Secretary shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a

comprehensive and detailed written report with respect to—

(1) the processing, storage, handling, and distribution of eggs and egg products subject to the provisions of this chapter; the inspection of establishments operated in connection therewith; the effectiveness of the operations of the inspection, including the effectiveness of the operations of State egg inspection programs; and recommendations for legislation to improve such program; and

(2) the administration of section 1046 of this title (relating to imports) during the immediately preceding calendar year, including but not limited to—

(A) a certification by the Secretary that foreign plants exporting eggs or egg products to the United States have complied with requirements of this chapter and regulations issued thereunder;

(B) the names and locations of plants authorized or permitted to export eggs or egg products to the United States;

(C) the number of inspectors employed by the Department of Agriculture in the calendar year concerned who were assigned to inspect plants referred to in paragraph (B) hereof and the frequency with which each such plant was inspected by such inspectors;

(D) the number of inspectors that were licensed by each country from which any imports were received and that were assigned, during the calendar year concerned, to inspect such imports and the facilities in which such imports were handled; and the frequency and effectiveness of such inspections;

(E) the total volume of eggs and egg products which was imported into the United States during the calendar year concerned from each country, including a separate itemization of the volume of each major category of such imports from each country during such year, and a detailed report of rejections of plants and products because of failure to meet appropriate standards prescribed by this chapter; and

(F) recommendations for legislation to improve such program.

(Pub. L. 91-597, § 26, Dec. 29, 1970, 84 Stat. 1634; S. Res. 4, Feb. 4, 1977.)

REFERENCES IN TEXT

This chapter, referred to in pars. (1), (2)(A), (E), was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter and amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

CHANGE OF NAME

The Committee on Agriculture and Forestry of the Senate was abolished and replaced by the Committee on Agriculture, Nutrition, and Forestry of the Senate, effective Feb. 11, 1977. See rule XXV of the Standing Rules of the Senate, as amended by Senate Resolution 4 (popularly cited as the "Committee System Reorganization Amendments of 1977"), approved Feb. 4, 1977.

§ 1055. Authorization of appropriations

Such sums as are necessary to carry out the provisions of this chapter are hereby authorized to be appropriated.

(Pub. L. 91-597, § 27, Dec. 29, 1970, 84 Stat. 1635.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

§ 1056. Separability of provisions

If any provision of this chapter or the application thereof to any person or circumstances is held invalid, the validity of the remainder of the chapter and of the application of such provision to other persons and circumstances shall not be affected thereby.

(Pub. L. 91-597, § 28, Dec. 29, 1970, 84 Stat. 1635.)

REFERENCES IN TEXT

This chapter, referred to in text, was, in the original, this Act, meaning Pub. L. 91-597, Dec. 29, 1970, 84 Stat. 1620, which enacted this chapter, amended sections 633 and 636 of Title 15, Commerce and Trade, and enacted provisions set out as notes under section 1031 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 1031 of this title and Tables volume.

CHAPTER 16—DRUG ABUSE PREVENTION AND TREATMENT

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1176. Formula grants.
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(b) Use of grants for certain purposes; limitation of State administrative expenses.
(c) State allotments: basis; minimum amount; procedure for determination; unobligated amounts, fiscal year availability; reallotment of unobligated amounts: basis; fiscal year availability.
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(a) Civil Service Commission responsibility for policies and services; use of existing governmental facilities.
(b) Similar programs and services in non-Federal government and private industry.
(c) Disqualification solely on ground of prior drug abuse prohibited; certain agencies, national security employment, and sensitive positions excepted from restriction.
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SUBCHAPTER V—NATIONAL INSTITUTE ON DRUG ABUSE

1191. Administration of programs.
(a) Establishment of the National Institute on Drug Abuse; functions; drug abuse prevention, treatment and rehabilitation programs.
(b) Appointment of Director and employment and functions of officers and employees of Institute.
(c) Participation of certain related disciplines in programs of Institute.
1192. Coordination, information, assistance and assignment activities and services.
(a) Coordination of prevention functions; central clearinghouse for information and assistance.
(b) Technical assistance to State and local agencies; local programs for analysis and resolutions; conferences, expenses; model legislation; uniform procedures, criteria and forms.
(c) Task forces.
1193. Research and development: encouragement; clinical research facilities: establishment; authorization of appropriations.

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in title 7 section 2012; title 38 section 4134.

SUBCHAPTER I—GENERAL PROVISIONS

§ 1101. Congressional findings

The Congress makes the following findings:

(1) Drug abuse is rapidly increasing in the United States and now afflicts urban, suburban, and rural areas of the Nation.

(2) Drug abuse seriously impairs individual, as well as societal, health and well-being.

(3) Drug abuse, especially heroin addiction, substantially contributes to crime.

(4) The adverse impact of drug abuse inflicts increasing pain and hardship on individuals, families, and communities and undermines our institutions.

(5) Too little is known about drug abuse, especially the causes, and ways to treat and prevent drug abuse.

(6) The success of Federal drug abuse programs and activities requires a recognition that education, treatment, rehabilitation, research, training, and law enforcement efforts are interrelated.

(7) The effectiveness of efforts by State and local governments and by the Federal Government to control and treat drug abuse in the United States has been hampered by a lack of coordination among the States, between States and localities, among the Federal Government, States and localities, and throughout the Federal establishment.

(8) Control of drug abuse requires the development of a comprehensive, coordinated long-term Federal strategy that encompasses both effective law enforcement against illegal drug traffic and effective health programs to rehabilitate victims of drug abuse.

(9) The increasing rate of drug abuse constitutes a serious and continuing threat to national health and welfare, requiring an immediate and effective response on the part of the Federal Government.

(10) Although the Congress observed a significant apparent reduction in the rate of increase of drug abuse during the three-year period subsequent to March 21, 1972, and in certain areas of the country apparent temporary reductions in its incidence, the increase and spread of heroin consumption since 1974, and the continuing abuse of other dangerous drugs, clearly indicate the need for effective, ongoing, and highly visible Federal leadership in the formation and execution of a comprehensive, coordinated drug abuse policy.

(Pub. L. 92-255, title I, § 101, Mar. 21, 1972, 86 Stat. 66; Pub. L. 94-237, § 1, Mar. 19, 1976, 90 Stat. 241.)

AMENDMENTS

1976—Par. (10). Pub. L. 94-237 added par. (10).

SHORT TITLE

Section 1 of Pub. L. 92-255 provided that: "This Act [which enacted this chapter, and amended sections 5313, 5315, and 5316 of Title 5, Government Organization and Employees, and sections 218, 246, 257, 2684, 2688a, 2688k, 2688n-1, and 2688t of Title 42, The Public Health and Welfare] may be cited as the 'Drug Abuse Office and Treatment Act of 1972'."

§ 1102. Declaration of national policy

The Congress declares that it is the policy of the United States and the purpose of this chapter to focus the comprehensive resources of the Federal Government and bring them to bear on drug abuse with the objective of significantly reducing the incidence, as well as the social and personal costs, of drug abuse in the United States, and to develop and assure the implementation of a comprehensive, coordinated long-term Federal strategy to combat drug abuse.

(Pub. L. 92-255, title I, § 102, Mar. 21, 1972, 86 Stat. 66; Pub. L. 94-237, § 2, Mar. 19, 1976, 90 Stat. 241.)

REFERENCES IN TEXT

This chapter, referred to in text, was in the original, this Act, meaning Pub. L. 92-255, Mar. 21, 1972, 86 Stat. 65, known as the Drug Abuse Office and Treatment Act of 1972, which enacted this chapter, and amended sections 5313, 5315, and 5316 of Title 5, Government Organization and Employees, and sections 218, 246, 257, 2684, 2688a, 2688k, 2688n-1, and 2688t of Title 42, The Public Health and Welfare. For complete classification to this Act to the Code, see Short Title note under section 1101 of this title and Tables volume.

AMENDMENTS

1976—Pub. L. 94-237 substituted "objective of significantly reducing the incidence, as well as the social and personal costs, of drug abuse in the United States, and to develop and assure the implementation of" for "immediate objective of significantly reducing the incidence of drug abuse in the United States within the shortest possible period of time, and to develop".

§ 1103. Definitions

(a) The definitions set forth in this section apply for the purposes of this chapter.

(b) The term "drug abuse prevention function" means any program or activity relating to drug abuse education or training (including preventive efforts directed to individuals who are not users of drugs and to individuals who are marginal users of drugs), treatment, rehabilitation, or research, and includes any such function even when performed by an organization whose primary mission is in the field of drug traffic prevention functions, or is unrelated to drugs. The term does not include any function defined in subsection (c) of this section as a "drug traffic prevention function".

(c) The term "drug traffic prevention function" means—

(1) the conduct of formal or informal diplomatic or international negotiations at any level, whether with foreign governments, other foreign governmental or nongovernmental persons or organizations of any kind, or any international organization of any kind, relating to traffic (whether licit or illicit) in drugs subject to abuse, or any measures to control or curb such traffic; or

(2) any of the following law enforcement activities or proceedings:

(A) the investigation and prosecution of drug offenses;

(B) the impanelment of grand juries;

(C) programs or activities involving international narcotics control; and

(D) the detection and suppression of illicit drug supplies.

(d) The term "drug abuse function" means any function described in subsection (b) or (c) of this section, or both.

(Pub. L. 92-255, title I, § 103, Mar. 21, 1972, 86 Stat. 67; Pub. L. 94-237, §§ 3, 4(a), Mar. 19, 1976, 90 Stat. 241.)

REFERENCES IN TEXT

This chapter, referred to in subsec. (a), was in the original, this Act, meaning Pub. L. 92-255, Mar. 21, 1972, 86 Stat. 65, known as the Drug Abuse Office and Treatment Act of 1972, which enacted this chapter, and amended sections 5313, 5315, and 5316 of Title 5, Government Organization and Employees, and sections 218, 246, 257, 2684, 2688a, 2688k, 2688n-1, and 2688t of Title 42, The Public Health and Welfare. For complete classification to this Act to the Code, see Short Title note under section 1101 of this title and Tables volume.

AMENDMENTS

1976—Subsec. (b). Pub. L. 94-237, § 3, substituted "education or training (including preventive efforts directed to individuals who are not users of drugs and to individuals who are marginal users of drugs)," for "education, training,".

Subsec. (d). Pub. L. 94-237, § 4(a), added subsec. (d).

§ 1104. Repealed. Pub. L. 94-237, § 4(c)(1), Mar. 19, 1976, 90 Stat. 244

Section, Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, provided, effective June 30, 1975, that the Special Action Office for Drug Abuse Prevention, each of the positions in the Office of Director, Deputy Director, and Assistant Director, and the National Advisory Council for Drug Abuse Prevention are abolished and subchapter II of this chapter is repealed.

SUBCHAPTER II—OFFICE OF DRUG ABUSE POLICY

PART 1—GENERAL PROVISIONS

§ 1111. Office of Drug Abuse Policy; establishment; Congressional access to information, documents, studies, and personnel of the Office

There is established in the Executive Office of the President an office to be known as the Office of Drug Abuse Policy (hereinafter in this chapter referred to as the "Office"). The establishment of the Office in the Executive Office of the President shall not be construed as affecting access by the Congress, or committees of either House, (1) to information, documents, and studies in the possession of, or conducted by, the Office or (2) to personnel of the Office.

(Pub. L. 92-255, title II, § 201, as added Pub. L. 94-237, § 4(b), Mar. 19, 1976, 90 Stat. 242.)

REFERENCES IN TEXT

This chapter, referred to in text, was in the original, this Act, meaning Pub. L. 92-255, Mar. 21, 1972, 86 Stat. 65, known as the Drug Abuse Office and Treatment Act of 1972, which enacted this chapter, and amended sections 5313, 5315, and 5316 of Title 5, Government Organization and Employees, and sections 218, 246, 257, 2684, 2688a, 2688k, 2688n-1, and 2688t of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note under section 1101 of this title and Tables volume.

PRIOR PROVISIONS

A prior section 1111, Pub. L. 92-255, title II, § 201, Mar. 21, 1972, 86 Stat. 67, which provided for the establishment of the Special Action Office for Drug Abuse Prevention, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

§ 1112. Director; appointment

The Office shall be headed by a Director who shall be appointed by the President, by and with the advice and consent of the Senate. The Director shall not hold office in any other department or agency of the United States, whether on an acting basis or otherwise, except on such occasions as may be appropriate in connection with the performance of such duties as may be assigned to him pursuant to section 1132 of this title.

(Pub. L. 92-255, title II, § 202, as added Pub. L. 94-237, § 4(b), Mar. 19, 1976, 90 Stat. 242.)

PRIOR PROVISIONS

A prior section 1112, Pub. L. 92-255, title II, § 202, Mar. 21, 1972, 86 Stat. 68, which provided for the appointment of a Director, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

§ 1113. Deputy Director; appointment; functions; acting Director

There shall be in the Office a Deputy Director who shall be appointed by the President, by and with the advice and consent of the Senate. The Deputy Director shall perform such functions as the Director may assign or delegate, and shall act as Director during the absence or disability of the Director or in the event of a vacancy in the office of Director.

(Pub. L. 92-255, title II, § 203, as added Pub. L. 94-237, § 4(b), Mar. 19, 1976, 90 Stat. 242.)

PRIOR PROVISIONS

A prior section 1113, Pub. L. 92-255, title II, § 203, Mar. 21, 1972, 86 Stat. 68, which provided for the appointment of a Deputy Director, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

§ 1114. Delegation of functions

Unless specifically prohibited by law, the Director may, without being relieved of his responsibility, perform any of his functions or duties or exercise any of his powers through, or with the aid of, such persons in, or organizations of, the Office as he may designate.

(Pub. L. 92-255, title II, § 204, as added Pub. L. 94-237, § 4(b), Mar. 19, 1976, 90 Stat. 242.)

PRIOR PROVISIONS

A prior section 1114, Pub. L. 92-255, title II, § 204, Mar. 21, 1972, 86 Stat. 68, which provided for the appointment of six Assistant Directors, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

§ 1115. Officers and employees

(a) Employment; functions; travel expenses

The Director may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to perform the functions vested in him. At the discretion of the Director, any officer or employee of the Office may be allowed and paid travel expenses, including per diem in lieu of subsistence, in the same manner as is authorized by section 5703 of title 5 for individuals employed intermittently.

(b) Additional positions in grades GS-16, 17, and 18 of the General Schedule

In addition to the number of positions which may be placed in grades GS-16, GS-17, and GS-18 under section 5108 of title 5, and without prejudice to the placement of other positions in the Office in such grades under any authority other than this subsection, not to exceed four positions in the Office may be placed in grades GS-16, GS-17, and GS-18, but in accordance with the standards and procedures prescribed by chapter 51 of such title.

(Pub. L. 92-255, title II, § 205, as added Pub. L. 94-237, § 4(b), Mar. 19, 1976, 90 Stat. 242.)

REFERENCES IN TEXT

Grades GS-16, GS-17, and GS-18, referred to in subsec. (b), are contained in the General Schedule which is set out under section 5332 of Title 5, Government Organization and Employees.

PRIOR PROVISIONS

A prior section 1115, Pub. L. 92-255, title II, § 205, Mar. 21, 1972, 86 Stat. 68, which provided for the delegation of functions by the Director, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

§ 1116. Experts and consultants; employment; compensation; numerical limitation

The Director may procure services as authorized by section 3109 of title 5, and may pay a rate for such services not in excess of the rate in effect for grade GS-18 of the General Schedule. The Director may employ individuals under this section without regard to any limitation, applicable to services procured under such section 3109, on the number of days or the period of such services, except that, at any one time, not more than six individuals may be employed under this section without regard to such limitation.

(Pub. L. 92-255, title II, § 206, as added Pub. L. 94-237, § 4(b), Mar. 19, 1976, 90 Stat. 242.)

REFERENCES IN TEXT

The General Schedule, referred to in text, is set out under section 5332 of Title 5, Government Organization and Employees.

PRIOR PROVISIONS

A prior section 1116, Pub. L. 92-255, title II, § 206, Mar. 21, 1972, 86 Stat. 68, which provided for the employment and prescription of functions for officers and employees by the Director, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

§ 1117. Acceptance of uncompensated services

The Director is authorized to accept and employ in furtherance of the purpose of this chapter voluntary and uncompensated services notwithstanding the provisions of section 665(b) of title 31.

(Pub. L. 92-255, title II, § 207, as added Pub. L. 94-237, § 4(b), Mar. 19, 1976, 90 Stat. 243.)

REFERENCES IN TEXT

This chapter, referred to in text, was in the original, this Act, meaning Pub. L. 92-255, Mar. 21, 1972, 86 Stat. 65, known as the Drug Abuse Office and Treatment Act of 1972, which enacted this chapter, and amended sections 5313, 5315, and 5316 of Title 5, Government Organization and Employees, and sections 218, 246, 257, 2684, 2688a, 2688k, 2688n-1, and 2688t of Title 42, The Public Health and Welfare. For complete classification to this Act to the Code, see Short Title note under section 1101 of this title and Tables volume.

PRIOR PROVISIONS

A prior section 1117, Pub. L. 92-255, title II, § 207, Mar. 21, 1972, 86 Stat. 68, which provided for the procurement of experts and consultants by the Director, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

§ 1118. Notice relating to the control of dangerous drugs

Whenever the Attorney General determines that there is evidence that—

(1) a drug or other substance, which is not a controlled substance (as defined in section 802(6) of this title), has a potential for abuse, or

(2) a controlled substance should be transferred or removed from a schedule under section 812 of this title,

he shall, prior to initiating any proceeding under section 811(a) of this title, give the Director timely notice of such determination. Information forwarded to the Attorney General pursuant to section 811(f) of this title shall also be forwarded by the Secretary of Health, Education, and Welfare to the Director.

(Pub. L. 92-255, title II, § 208, as added Pub. L. 94-237, § 4(b), Mar. 19, 1976, 90 Stat. 243.)

PRIOR PROVISIONS

A prior section 1118, Pub. L. 92-255, title II, § 208, Mar. 21, 1972, 86 Stat. 68, which provided for the acceptance of uncompensated services by the Director, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

§ 1119. Statutory requirements and authorities unaffected

Nothing in this subchapter shall be construed to limit the authority of the Secretary of Defense with respect to the operation of the Armed Forces or the authority of the Administrator of Veterans' Affairs with respect to the furnishing of health care and related services to veterans.

(Pub. L. 92-255, title II, § 210, as added Pub. L. 94-237, § 4(b), Mar. 19, 1976, 90 Stat. 243.)

PRIOR PROVISIONS

A prior section 1119, Pub. L. 92-255, title II, § 209, Mar. 21, 1972, 86 Stat. 68, which provided for notice by the Attorney General to the Director with respect to the control of dangerous drugs, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

A prior section 210 of Pub. L. 92-255, title II, Mar. 21, 1972, 86 Stat. 69, which provided for the authority of the Director to make grants and enter into contract, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1976.

§ 1120. Authorization of appropriations

For purposes of carrying out this subchapter, there is authorized to be appropriated $700,000 for the fiscal year ending June 30, 1976, $500,000 for the period July 1, 1976, through September 30, 1976, $2,000,000 for the fiscal

year ending September 30, 1977, and $2,000,000 for the fiscal year ending September 30, 1978.

(Pub. L. 92-255, title II, § 211, as added Pub. L. 94-237, § 4(b), Mar. 19, 1976, 90 Stat. 243.)

PRIOR PROVISIONS

A prior section 1120, Pub. L. 92-255, title II, § 210, Mar. 21, 1972 86 Stat. 69, which provided for the authority of the Director to make grants and enter into contracts, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

A prior section 211 of Pub. L. 92-255, title II, Mar. 21, 1972, 86 Stat. 69, which provided for the appointment of an acting Director until the position was initially filled, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

§§ 1121 to 1123. Repealed. Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67

Section 1121, Pub. L. 92-255, title II, § 211, Mar. 21, 1972, 86 Stat. 69, provided for the appointment of an acting Director until the position was initially filled.

Section 1122, Pub. L. 92-255, title II, § 213, Mar. 21, 1972, 86 Stat. 69, prohibited the Director or any other Federal officer from waiving or disregarding any limitation or requirement prescribed by law with respect to any Federal program or activity.

Section 1123, Pub. L. 92-255, title II, § 214, Mar. 21, 1972, 86 Stat. 70, provided for the authorization of appropriations, and fiscal year availability of such appropriations.

EFFECTIVE DATE OF REPEAL

Section 1104 of this title, prior to repeal by section 4(c)(1) of Pub. L. 94-237, provided for repeal of sections effective June 30, 1975.

PART 2—FUNCTIONS OF THE DIRECTOR

§ 1131. Concentration of Federal effort

(a) Planning and policies; coordination of Federal prevention and related functions

The Director shall make recommendations to the President with respect to policies for, objectives of, and establishment of priorities for, Federal drug abuse functions and shall coordinate the performance of such functions by Federal departments and agencies. Recommendations under this subsection shall include recommendations for changes in the organization, management, and personnel of Federal departments and agencies performing drug abuse functions to implement the policies, priorities, and objectives recommended under this subsection.

(b) Operating agencies; considerations respecting consistency, additions, and changes; evaluations and studies of performance and achievements; construction of drug abuse as health problem

To carry out subsection (a), of this section, the Director shall—

(1) review the regulations, guidelines, requirements, criteria, and procedures of Federal departments and agencies applicable to the performance of drug abuse functions;

(2) conduct, or provide for, evaluations of (A) the performance of drug abuse functions by Federal departments and agencies, and (B) the results achieved by such departments and agencies in the performance of such functions; and

(3) seek to assure that Federal departments and agencies, in the performance of drug abuse functions, construe drug abuse as a health problem.

(c) Information and reports respecting prevention functions

Federal departments and agencies engaged in drug abuse functions shall submit to the Director such information and reports with respect to such functions as he may reasonably require to carry out the purposes of this subchapter.

(Pub. L. 92-255, title II, § 221, as added Pub. L. 94-237, § 4(b), Mar. 19, 1976, 90 Stat. 243.)

PRIOR PROVISIONS

A prior section 1131, Pub. L. 92-255, title II, § 221, Mar. 21, 1972, 86 Stat. 70, which provided for the establishment of overall planning and policy and the criteria to achieve the objectives and priorities for all Federal drug abuse prevention functions, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1172 of this title.

§ 1132. International negotiations

The President may designate the Director to represent the Government of the United States in discussions and negotiations relating to drug abuse functions.

(Pub. L. 92-255, title II, § 222, as added Pub. L. 94-237, § 4(b), Mar. 19, 1976, 90 Stat. 244.)

PRIOR PROVISIONS

A prior section 1132, Pub. L. 92-255, title II, § 222, Mar. 21, 1972, 86 Stat. 71, which provided for the review and modification of implementation plans and budget requests, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1112 of this title.

§ 1133. Annual report to President and Congress; contents; accounting of funds

The Director shall submit to the President and the Congress, prior to March 1 of each year which begins after March 19, 1976, a written report on the activities of the Office. The report shall specify the objectives, activities, and accomplishments of the Office, and shall contain an accounting of funds expended under this subchapter.

(Pub. L. 92-255, title II, § 223, as added Pub. L. 94-237, § 4(b), Mar. 19, 1976, 90 Stat. 244.)

PRIOR PROVISIONS

A prior section 1133, Pub. L. 92-255, title II, § 223, Mar. 21, 1972, 86 Stat. 71, which provided for the establishment and the objectives of a Special Fund, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

§§ 1134 to 1143. Repealed. Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67

Section 1134, Pub. L. 92-255, title II, § 224, Mar. 21, 1972, 86 Stat. 71, provided for the establishment of research and development programs by the Director.

Section 1135, Pub. L. 92-255, title II, § 225, Mar. 21, 1972, 86 Stat. 72, provided for the establishment of a single non-Federal share requirement.

Section 1136, Pub. L. 92-255, title II, § 226, Mar. 21, 1972, 86 Stat. 72, provided for the Director to make drug prevention function recommendations to the President and to consult with responsible agencies with respect to drug prevention functions.

Section 1137, Pub. L. 92-255, title II, § 227, Mar. 21, 1972, 86 Stat. 72, provided for the resolution of agency conflicts with regard to drug prevention functions.

Section 1138, Pub. L. 92-255, title II, § 228, Mar. 21, 1972, 86 Stat. 72, provided for communications and liaison with respect to drug prevention functions by one of the Assistant Directors.

Section 1139, Pub. L. 92-255, title II, § 229, Mar. 21, 1972, 86 Stat. 72, provided, with respect to drug prevention functions, coordination of State and local governments, availability of information and other services and activities.

Section 1140, Pub. L. 92-255, title II, § 230, Mar. 21, 1972, 86 Stat. 73, provided for a management oversight review by a Federal officer.

Section 1141, Pub. L. 92-255, title II, § 231, Mar. 21, 1972, 86 Stat. 73, provided for the convening of a council of officials of Federal agencies responcible for drug prevention functions by the Director.

Section 1142, Pub. L. 92-255, title II, § 232, Mar. 21, 1972, 86 Stat. 73, provided for the designation of the Director to represent the Government in international negotiations related to drug prevention functions.

Section 1143, Pub. L. 92-255, title II, § 233, Mar. 21, 1972, 86 Stat. 73, provided for an annual written report to the President by the Director.

EFFECTIVE DATE OF REPEAL

Section 1104 of this title, prior to repeal by section 4(c)(1) of Pub. L. 94-237, provided for repeal of sections effective June 30, 1975.

PART 3—NATIONAL ADVISORY COUNCIL FOR DRUG ABUSE PREVENTION

§§ 1151 to 1155. Repealed. Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67

Section 1151, Pub. L. 92-255, title II, § 251, Mar. 21, 1972, 86 Stat. 74, provided for the establishment of a National Advisory Council for Drug Abuse Prevention.

Section 1152, Pub. L. 92-255, title II, § 252, Mar. 21, 1972, 86 Stat. 74, provided for the membership of the National Advisory Council for Drug Abuse Prevention.

Section 1153, Pub. L. 92-255, title II, § 253, Mar. 21, 1972, 86 Stat. 74, provided for the designation of chairman of the National Advisory Council for Drug Abuse Prevention.

Section 1154, Pub. L. 92-255, title II, § 254, Mar. 21, 1972, 86 Stat. 74, provided for compensation and expenses for the members of the National Advisory Council for Drug Abuse Prevention.

Section 1155, Pub. L. 92-255, title II, § 255, Mar. 21, 1972, 86 Stat. 74, set forth the functions of the National Advisory Council for Drug Abuse Prevention.

EFFECTIVE DATE OF REPEAL

Section 1104 of this title, prior to repeal by section 4(c)(1) of Pub. L. 94-237, provided for repeal of sections effective June 30, 1975.

SUBCHAPTER III—NATIONAL DRUG ABUSE STRATEGY

§ 1161. Development of strategy requirement; initial promulgation of strategy

Immediately on March 21, 1972, the President shall direct the development of a comprehensive, coordinated long-term Federal strategy (hereinafter in this subchapter referred to as the "strategy") for all drug abuse prevention functions and all drug traffic prevention functions conducted, sponsored, or supported by any department or agency of the Federal Government. The strategy shall be initially promulgated by the President no later than nine months after March 21, 1972.

(Pub. L. 92-255, title III, § 301, Mar. 21, 1972, 86 Stat. 74.)

CODIFICATION

"Immediately on March 21, 1972," in the original read "Immediately upon the enactment of this title" [this subchapter].

§ 1162. Strategy Council; establishment; membership; interim member; review and commentary on strategy

To develop the strategy, the President shall establish a Strategy Council whose membership shall include the Director of the Office of Drug Abuse Policy, the Attorney General, the Secretaries of Health, Education, and Welfare, State, and Defense, the Administrator of Veterans' Affairs, other officials as the President may deem appropriate and no fewer than three members from outside the Federal Government. Until the date specified in section 1104 of this title, the Director shall provide such services as are required to assure that the strategy is prepared, and thereafter such services shall be provided by such officer or agency of the United States as the President may designate. The strategy shall be subject to review and written comment by those Federal officials participating in its preparation.

(Pub. L. 92-255, title III, § 302, Mar. 21, 1972, 86 Stat. 75; Pub. L. 94-237, § 4(c)(2), (3), (5)(A), Mar. 19, 1976, 90 Stat. 244.)

REFERENCES IN TEXT

Reference to the date specified in section 1104 of this title and to the Director are to June 30, 1975, the date of repeal of subchapter II of this chapter and abolition of the Special Action Office for Drug Abuse Prevention, and to the Director of Office of Drug Abuse Policy, respectively. Section 1104 of this title was repealed by section 4(c)(1) of Pub. L. 94-237.

AMENDMENTS

1976—Pub. L. 94-237 substituted "Office of Drug Abuse Policy" for "Special Action Office of Drug Abuse Prevention until the date specified in section 1104 of this title" and struck out "and" before "other officials", inserted "and no fewer than three members from outside the Federal Government" following "appropriate".

§ 1163. Contents of strategy

The strategy shall contain—

(1) an analysis of the nature, character, and extent of the drug abuse problem in the United States, including examination of the interrelationships between various approaches to solving the drug abuse problem and their potential for interacting both positively and negatively with one another;

(2) a comprehensive Federal plan, with respect to both drug abuse prevention functions and drug traffic prevention functions, which shall specify the objectives of the Federal strategy and how all available resources, funds, programs, services, and facilities authorized under relevant Federal law should be used; and

(3) an analysis and evaluation of the major programs conducted, expenditures made, results achieved, plans developed, and problems

encountered in the operation and coordination of the various Federal drug abuse prevention functions and drug traffic prevention functions.

(Pub. L. 92-255, title III, § 303, Mar. 21, 1972, 86 Stat. 75.)

§ 1164. Preparation of strategy

To facilitate the preparation of the strategy, the Council shall—

(1) engage in the planning necessary to achieve the objectives of a comprehensive, coordinated long-term Federal strategy, including examination of the overall Federal investment to combat drug abuse;

(2) at the request of any member, require departments and agencies engaged in Federal drug abuse prevention functions and drug traffic prevention functions to submit such information and reports and to conduct such studies and surveys as are necessary to carry out the purposes of this subchapter, and the departments and agencies shall submit to the Council and to the requesting member the information, reports, studies, and surveys so required;

(3) evaluate the performance and results achieved by Federal drug abuse prevention functions and drug traffic prevention functions and the prospective performance and results that might be achieved by programs and activities in addition to or in lieu of those currently being administered.[1]

(4) from time to time make recommendations to, and coordinate with, the Director of the Office of Drug Abuse Policy with respect to the performance of his functions under this chapter.

(Pub. L. 92-255, title III, § 304, Mar. 21, 1972, 86 Stat. 75; Pub. L. 94-237, § 4(c)(4), Mar. 19, 1976, 90 Stat. 244.)

References in Text

This chapter, referred to in par. (4), was in the original, this Act, meaning Pub. L. 92-255, Mar. 21, 1972, 86 Stat. 65, known as the Drug Abuse Office and Treatment Act of 1972, which enacted this chapter, and amended sections 5313, 5315, and 5316 of Title 5, Government Organization and Employees, and sections 218, 246, 257, 2684, 2688a, 2688k, 2688n-1, and 2688t of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note under section 1101 of this title and Tables volume.

Amendments

1976—Par. (4). Pub. L. 94-237 added par. (4).

§ 1165. Review, revision, and promulgation of strategy

The strategy shall be reviewed, revised as necessary, and promulgated as revised prior to June 1 of each year.

(Pub. L. 92-255, title III, § 305, Mar. 21, 1972, 86 Stat. 75; Pub. L. 94-237, § 5, Mar. 19, 1976, 90 Stat. 244.)

Amendments

1976—Pub. L. 94-237 substituted "prior to June 1 of each year" for "from time to time as the President deems appropriate, but not less often than once a year".

[1] So in original, the period should be a semicolon.

SUBCHAPTER IV—OTHER FEDERAL PROGRAMS

§ 1171. Drug abuse prevention function appropriations

Any request for appropriations by a department or agency of the Government submitted after March 21, 1972, shall specify (1) on a line item basis, that part of the appropriations which the department or agency is requesting to carry out its drug abuse prevention functions, and (2) the authorization of the appropriations requested to carry out each of its drug abuse prevention functions.

(Pub. L. 92-255, title IV, § 404, Mar. 21, 1972, 86 Stat. 77.)

§ 1172. Special reports by the Secretary of Health, Education, and Welfare

(a) The Secretary of Health, Education, and Welfare (hereinafter in this subchapter referred to as the "Secretary") shall develop and submit to the Congress and the Director within ninety days after March 21, 1972, a written plan for the administration and coordination of all drug abuse prevention functions within the Department of Health, Education, and Welfare. Such report shall list each program conducted and each service provided in carrying out such functions, describe how such programs and services are to be coordinated, and describe the steps taken or to be taken to insure that such programs and services will be administered so as to encourage the broadest possible participation of professionals and paraprofessionals in the fields of medicine, science, the social sciences, and other related disciplines. The plan shall be consistent with the policies, priorities, and objectives established by the Director under section 1131 of this title.

(b) The Secretary shall submit to the Director, for inclusion in the annual report required by section 1143 of this title, a report describing model and experimental methods and programs for the treatment and rehabilitation of drug abusers, and describing the advantages of each such method and program and an evaluation of the success or failure of each such method or program. The Secretary's report shall contain recommendations for the development of new and improved methods and programs for the treatment and rehabilitation of drug abusers, for community implementation of such methods and programs, and for such legislation and administrative action as he deems appropriate.

(Pub. L. 92-255, title IV, § 405, Mar. 21, 1972, 86 Stat. 77.)

References in Text

Section 1143 of this title, referred to in subsec. (b), was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67.

§ 1173. Additional drug abuse prevention functions of the Secretary of Health, Education, and Welfare

(a) Information center; uniform methodology and technology; statistics; review and evaluation of State plans

The Secretary shall—

(1) operate an information center for the collection, preparation, and dissemination of

all information relating to drug abuse prevention functions, including information concerning State and local drug abuse treatment plans, and the availability of treatment resources, training and educational programs, statistics, research, and other pertinent data and information;

(2) investigate and publish information concerning uniform methodology and technology for determining the extent and kind of drug use by individuals and effects which individuals are likely to experience from such use;

(3) gather and publish statistics pertaining to drug abuse and promulgate regulations specifying uniform statistics to be furnished, records to be maintained, and reports to be submitted, on a voluntary basis by public and private entities and individuals respecting drug abuse; and

(4) review, and publish an evaluation of, the adequacy and appropriateness of any provision relating to drug abuse prevention functions contained in the comprehensive State health, welfare, or rehabilitation plans submitted to the Federal Government pursuant to Federal law, including, but not limited to, those submitted pursuant to section 5(a) of the Vocational Rehabilitation Act, sections 314(d)(2)(K) and 604(a) of the Public Health Service Act [42 U.S.C. 246(d)(2)(K) and 291d(a)], section 1902(a) of title XIX of the Social Security Act [42 U.S.C. 1396a(a)], and section 204(a) of part A of the Community Mental Health Centers Act.

(b) Execution of functions through National Institute on Drug Abuse

After December 31, 1974, the Secretary shall carry out his functions under subsection (a) of this section through the National Institute on Drug Abuse.

(Pub. L. 92-255, title IV, § 406, Mar. 21, 1972, 86 Stat. 78.)

REFERENCES IN TEXT

Section 5(a) of the Vocational Rehabilitation Act, referred to in subsec. (a)(4), which set forth requirements for approval of State plans, was formerly classified to section 35(a) of Title 29, Labor. The Vocational Rehabilitation Act is act June 2, 1920, ch. 219, 41 Stat. 735, which was classified generally to chapter 4 (§ 31 et seq.) of Title 29, was repealed by section 500(a) of Pub. L. 93-112, title V, Sept. 26, 1973, 87 Stat. 390 (known as the Rehabilitation Act of 1973), which is classified to section 701 et seq. of Title 29. Section 500(a) of Pub. L. 93-112 also provided in part that references to the Vocational Rehabilitation Act in any other provision of law shall be deemed to be references to the Rehabilitation Act of 1973. Provisions relating to the approval of state plans are now contained in section 101 of the Rehabilitation Act of 1973, which is classified to section 721(a) of Title 29.

Section 204(a) of part A of the Community Mental Health Centers Act, referred to in subsec. (a)(4), which set forth requirements for submission and approval of State plans, was formerly classified to section 2684(a) of Title 42, The Public Health and Welfare. Part A of the Community Mental Health Centers Act was revised generally by Pub. L. 94-63, title III, § 303, July 29, 1975, 89 Stat. 309, and is classified generally to section 2689 et seq. of Title 42. Provisions relating to the submission and approval of State plans are now contained in section 206(a) of part A of the Community Mental Health Centers Act, which is classified to section 2689e(a) of Title 42.

§ 1174. Discrimination against drug abusers by general hospitals prohibited; regulations; suspension or revocation of federal support

(a) Drug abusers who are suffering from medical conditions shall not be discriminated against in admission or treatment, solely because of their drug abuse or drug dependence, by any private or public general hospital which receives support in any form from any program supported in whole or in part by funds appropriated to any Federal department or agency.

(b)(1) The Secretary is authorized to make regulations for the enforcement of the policy of subsection (a) of this section with respect to the admission and treatment of drug abusers in hospitals which receive support of any kind from any program administered by the Secretary. Such regulations shall include procedures for determining (after opportunity for a hearing if requested) if a violation of subsection (a) of this section has occurred, notification of failure to comply with such subsection, and opportunity for a violator to comply with such subsection. If the Secretary determines that a hospital subject to such regulations has violated subsection (a) of this section and such violation continues after an opportunity has been afforded for compliance, the Secretary may suspend or revoke, after opportunity for a hearing, all or part of any support of any kind received by such hospital from any program administered by the Secretary. The Secretary may consult with the officials responsible for the administration of any other Federal program from which such hospital receives support of any kind, with respect to the suspension or revocation of such other Federal support for such hospital.

(2) Superseded. Pub. L. 94-581, title I, § 111(c)(2), Oct. 21, 1976, 90 Stat. 2852.

(Pub. L. 92-255, title IV, § 407, Mar. 21, 1972, 86 Stat. 78; Pub. L. 94-237, § 6(a), Mar. 19, 1976, 90 Stat. 244; Pub. L. 94-581, title I, § 111(c)(2), Oct. 21, 1976, 90 Stat. 2852.)

AMENDMENTS

1976—Subsec. (a). Pub. L. 94-237 struck out "emergency" following "suffering from" and substituted "discriminated against in" for "refused".

Subsec. (b)(1). Pub. L. 94-237 redesignated existing provisions as subsec. (b)(1), and in subsec. (b)(1), as so redesignated, added provision relating to the administration and treatment of drug abusers in hospitals which receive support of any kind from any program administered by the Secretary.

Subsec. (b)(2). Pub. L. 94-581 provided that subsec. (b)(2), which directed the Administrator of Veterans' Affairs, through the Chief Medical Director to prescribe regulations making applicable the regulations prescribed by the Secretary under subsec. (b)(1) to the provision of hospital care, nursing home care, domiciliary care, and medical services under Title 38 to veterans suffering from drug abuse or drug dependence and to consult with the Secretary in order to achieve the maximum possible coordination, of the regulations, and the implementation thereof, which they each prescribed, was superseded by section 4131 et seq. of Title 38, Veterans' Benefits.

Pub. L. 94-237 added subsec. (b)(2).

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94-581 effective Oct. 21, 1976, see section 211 of Pub. L. 94-581, set out as an Effective Date of 1976 Amendment note under section 111 of Title 38, Veterans' Benefits.

REPORT OF ADMINISTRATOR OF VETERANS' AFFAIRS TO CONGRESSIONAL COMMITTEES; PUBLICATION IN FEDERAL REGISTER

Section 6(b) of Pub. L. 94-237, which directed the Administrator of Veterans' Affairs to submit to the appropriate committees of the House of Representatives and the Senate a full report (1) on the regulations (including guidelines, policies, and procedures thereunder) he had prescribed pursuant to section 407(b)(2) of the Act [former subsec. (b)(2) of this section], (2) explaining the basis for any inconsistency between such regulations and regulations of the Secretary under section 407(b)(1) of the Act [subsec. (b)(1) of this section], (3) on the extent, substance, and results of his consultations with the Secretary respecting the prescribing and implementation of the Administrator's regulations, and (4) containing such recommendations for legislation and administrative actions as he determined were necessary and desirable, with the Administrator to submit the report not later than sixty days after the effective date of the regulations prescribed by the Secretary under such section 407(b)(1) and to publish such report in the Federal Register, was characterized by section 111(c)(6) of Pub. L. 94-581 as having been superseded by section 4134 of Title 38, Veterans' Benefits.

§ 1175. Confidentiality of patient records

(a) Disclosure authorization

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bonafide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Prohibition against use of record in making criminal charges or investigation of patient

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) Continuing prohibition against disclosure irrespective of status as patient

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) Armed Forces and Veterans' Administration; interchange of records

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

(f) Penalty for first and subsequent offenses

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) Regulations; interagency consultations; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders

Except as provided in subsection (h) of this section, the Secretary of Health, Education, and Welfare, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Pub. L. 92-255, title IV, § 408, Mar. 21, 1972, 86 Stat. 79; Pub. L. 93-282, title III, § 303(a), (b), May 14, 1974, 88 Stat. 137, 138; Pub. L. 94-237, § 4(c)(5)(A), Mar. 19, 1976, 90 Stat. 244; Pub. L. 94-581, title I, § 111(c)(3), Oct. 21, 1976, 90 Stat. 2852.)

AMENDMENTS

1976—Subsec. (g). Pub. L. 94-237 substituted "Office of Drug Abuse Policy" for "Special Action Office for Drug Abuse Prevention" in subsec. (g) as originally enacted by section 303(a) of Pub. L. 93-282 and in section 303(b)(1) of Pub. L. 93-282 which amended subsec. (g) of this section as originally enacted. See 1974 Amendment note hereunder. This substitution involves the text of subsec. (g) prior to the substitution of "Secretary of Health, Education, and Welfare" for "Director

of the Special Action Office for Drug Abuse Prevention" and, therefore, entails no change in text.

Subsec. (h). Pub. L. 94-581 provided that subsec. (h), which directed the Administrator of Veterans' Affairs, through the Chief Medical Director, to prescribe regulations making applicable the regulations established by the Secretary under subsection (g) of this section to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical services under Title 38 to veterans suffering from drug abuse and to consult with the Secretary in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribed, was superseded by section 4131 et seq. of Title 38, Veterans' Benefits.

1974—Subsec. (a). Pub. L. 93-282, § 303(a), substituted "drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed" for "drug abuse prevention function authorized or assisted under any provision of this Act or any Act amended by this Act shall be confidential and may be disclosed".

Subsec. (b)(1). Pub. L. 93-282, § 303(a), substituted provision for disclosure of content of a subsec. (a) record in accordance with prior written consent of the patient to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsec. (g) of this section for former provision for such disclosure with the patient's written consent to medical personnel for the purpose of diagnosis or treatment of the patient, and to governmental personnel for the purpose of obtaining benefits to which the patient was entitled.

Subsec. (b)(2). Pub. L. 93-282, § 303(a), substituted "Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent" for "If the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, does not give his written consent" and in cl. (B) substituted "management audits, financial audits," for "management or financial audits,".

Subsecs. (c), (d). Pub. L. 93-282, § 303(a), reenacted provisions without any change.

Subsec. (e). Pub. L. 93-282, § 303(a), added subsec. (e). Former subsec. (e) redesignated (f).

Subsec. (f). Pub. L. 93-282, § 303(a), redesignated former subsec. (e) as (f), deleted introductory text "Except as authorized under subsection (b) of this section," and substituted "Any person who violates any provision of this section or any regulation issued pursuant to this section" for "any person who discloses the contents of any record referred to in subsection (a) of this section".

Subsec. (g). Pub. L. 93-282, § 303(a), added subsec. (g).

Pub. L. 93-282, § 303(b)(1), (2)(A), substituted in first sentence "Secretary of Health, Education, and Welfare" for "Director of the Special Action Office for Drug Abuse Prevention", in second sentence "Secretary" for "Director", and introductory text "Except as provided in subsection (h) of this section, the" for "The", effective June 30, 1975.

Subsec. (h). Pub. L. 93-282, § 303(b)(2)(B), added subsec. (h), effective June 30, 1975.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94-581 effective Oct. 21, 1976, see section 211 of Pub. L. 94-581, set out as an Effective Date of 1976 Amendment note under section 111 of Title 38, Veterans' Benefits.

EFFECTIVE DATE OF 1974 AMENDMENT

Section 303(b)(1) and (2) of Pub. L. 93-282 provided that amendment of subsec. (g) by section 303(b)(1) and (2)(A) and enactment of subsec. (h) by section 303(b)(2)(B) of Pub. L. 93-282 shall be effective as provided for in section 1104 of this title namely June 30, 1975.

REGULATIONS ISSUED PRIOR TO JUNE 30, 1975, EFFECTIVE UNTIL REVOKED OR AMENDED

Section 303(d) of Pub. L. 93-282 as amended by section 4(c)(5)(B) of Pub. L. 94-237, Office of Drug Abuse Policy provided that: "Any regulation under or with respect to section 408 of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1175) issued by the Director of the Office of Drug Abuse Policy prior to the date specified in section 104 of that Act (21 U.S.C. 1104), [June 30, 1975], whether before or after the enactment of this Act [May 14, 1974], shall remain in effect until revoked or amended by the Director or the Secretary of Health, Education, and Welfare, as the case may be."

REPORT OF ADMINISTRATOR OF VETERANS' AFFAIRS TO CONGRESSIONAL COMMITTEES; PUBLICATION IN FEDERAL REGISTER

Section 303(c) of Pub. L. 93-282, which directed the Administrator of Veterans' Affairs to submit to the appropriate committees of the House of Representatives and the Senate a full report (1) on the regulations (including guidelines, policies, and procedures thereunder) he had prescribed pursuant to section 408(h) of the Drug Abuse Office and Treatment Act of 1972 [former subsec. (h) of this section as added by section 303(b)(2)(B) of Pub. L. 93-282], (2) explaining the bases for any inconsistency between such regulations and the regulations of the Secretary of Health, Education, and Welfare under section 408(g) of that Act [subsec. (g) of this section as added and amended by section 303(b)(1), (2)(A) of Pub. L. 93-282], (3) on the extent, substance, and results of his consultations with the Secretary respecting the prescribing and implementation of the Administrator's regulations, and (4) containing such recommendations for legislation and administrative actions as he determined were necessary and desirable, with the Administrator to submit the report not later than sixty days after the effective date of the regulations prescribed by the Secretary, was characterized by section 111(c)(7) of Pub. L. 94-581 as having been superseded by section 4134 of Title 38, Veterans' Benefits.

§ 1176. Formula grants

(a) Authorization of appropriations; "State" defined

There are authorized to be appropriated $15,000,000 for the fiscal year ending June 30, 1972, $30,000,000 for the fiscal year ending June 30, 1973, $40,000,000 for the fiscal year ending June 30, 1974, $45,000,000 for each of the fiscal years ending June 30, 1975, and June 30, 1976, $11,250,000 for the period July 1, 1976, through September 30, 1976, and $45,000,000 for each of the fiscal years ending September 30, 1977, and September 30, 1978, for grants to States in accordance with this section. For the purpose of this section, the term "State" includes the District of Columbia, the Virgin Islands, the Commonwealth of Puerto Rico, Guam, American Samoa, and the Trust Territory of the Pacific Islands, in addition to the fifty States.

(b) Use of grants for certain purposes; limitation of State administrative expenses

Grants to States may be made under this section—

(1) for the preparation of plans which are intended to meet the requirements of subsection (e) of this section;

(2) for the expenses (other than State administrative expenses) of (A) carrying out projects under and otherwise implementing plans approved by the Secretary pursuant to subsection (f) of this section, and (B) evaluat-

ing the results of such plans as actually implemented; and

(3) for the State administrative expenses of carrying out plans approved by the Secretary pursuant to subsection (f) of this section, except that no grant under this paragraph to any State for any year may exceed $50,000 or 10 per centum of the total allotment of that State for that year, whichever is less.

(c) State allotments: basis; minimum amount; procedure for determination; unobligated amounts, fiscal year availability; reallotment of unobligated amounts: basis; fiscal year availability

(1)(A) For each fiscal year the Secretary shall, in accordance with regulations, allot the sums appropriated pursuant to subsection (a) of this section for such year among the States on the basis of the relative population, financial need, and the need for more effective conduct of drug abuse prevention functions, except that no such allotment to any State (other than the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands), shall be less than $100,000 multiplied by a fraction whose numerator is the amount actually appropriated for the purposes of this section for the fiscal year for which the allotment is made, and whose denominator is the amount authorized to be appropriated by subsection (a) of this section for that year, except that in the case of a State (other than the Virgin Islands, Guam, American Samoa, and the Trust Territories of the Pacific Islands) which can demonstrate a need (determined in accordance with the methodology established under subparagraph (B)(iii) for a minimum allotment in excess of $100,000, multiplied by such fraction, the minimum allotment for such State may be increased by up to 50 percent in accordance with such demonstrated need.

(B)(i) Not later than June 15, of each year, the Secretary, after consultation with the Director of the National Institute on Drug Abuse, shall publish a notice of proposed rulemaking setting forth a formula to be used in making allotments pursuant to subparagraph (A) of this paragraph. Such notice of published rulemaking shall be in accordance with section 553 of title 5, except that a sixty-day period shall be allowed for public comment.

(ii) Not later than the first day of each fiscal year, the Secretary shall publish final regulations setting forth the allotment formula to be used pursuant to subparagraph (A) of this paragraph in making allotments during such fiscal year.

(iii) In determining, for the purposes of paragraph (1), the extent of need for more effective conduct of drug abuse prevention functions, the Secretary shall (within one hundred and eighty days after March 19, 1976) by regulation establish a methodology to assess and determine the incidence and prevalence of drug abuse to be applied in determining such need.

(2) Any amount allotted under paragraph (1) of this subsection to a State (other than the Virgin Islands, American Samoa, Guam, and the Trust Territory of the Pacific Islands) and remaining unobligated at the end of such year shall remain available to such State, for the purposes for which made, for the next fiscal year (and for such year only), and any such amount shall be in addition to the amounts allotted to such State for such purpose for such next fiscal year; except that any such amount remaining unobligated at the end of the sixth month following the end of such year for which it was allotted, which the Secretary determines will remain unobligated by the close of such next fiscal year, may be reallotted by the Secretary to be available for the purposes for which made until the close of such next fiscal year, to other States which have need therefor, on such basis as the Secretary deems equitable and consistent with the purposes of this section, and any amount so reallotted to a State shall be in addition to the amounts allotted and available to the States for the same period. Any amount allotted under paragraph (1) of this subsection to the Virgin Islands, American Samoa, Guam, or the Trust Territory of the Pacific Islands for a fiscal year and remaining unobligated at the end of such year shall remain available to it, for the purposes for which made, for the next two fiscal years (and for such years only), and any such amount shall be in addition to the amounts allotted to it for such purpose for each of such next two fiscal years; except that any such amount, remaining unobligated at the end of the first of such next two years, which the Secretary determines will remain unobligated at the close of the second of such next two years, may be reallotted by the Secretary, to be available for the purposes for which made until the close of the second of such next two years, to any other of such four States which have need therefor, on such basis as the Secretary deems equitable and consistent with the purposes of this section, and any amount so reallotted to a State shall be in addition to the amounts allotted and available to the State for the same period.

(d) Application for grants; submission and approval; form and contents

No grant may be made under subsection (b)(1) of this section unless an application therefor has been submitted to, and approved by, the Secretary. Such application shall be in such form, submitted in such manner, and contain such information, including assurances satisfactory to the Secretary that the grant will be used by the State for the preparation of a State plan which will meet the requirements of subsection (e) of this section, as the Secretary shall by regulation prescribe.

(e) State plans; requirements

Any State desiring to receive a grant under subsection (b)(2) or (b)(3) of this section shall submit to the Secretary, not later than July 15 of each calendar year, a State plan for planning, establishing, conducting, and coordinating projects for the development of more effective drug abuse prevention functions in the State and for evaluating the conduct of such functions in the State. Each State plan shall pertain to the twelve-month period commencing October 1 of the calendar year in which it is required to be submitted, and—

(1) designate or establish a single State agency as the sole agency for the preparation and administration of the plan, or for supervising the preparation and administration of the plan;

(2) contain satisfactory evidence that the State agency designated or established in accordance with paragraph (1) will have authority to prepare and administer, or supervise the preparation and administration of, such plan in conformity with this subsection;

(3) provide for the designation of a State advisory council which shall include representatives of nongovernmental organizations or groups, and of public agencies concerned with the prevention and treatment of drug abuse and drug dependence, from different geographical areas of the State, and which shall consult with the State agency in carrying out the plan;

(4) describe the drug abuse prevention functions to be carried out under the plan with assistance under this section;

(5)(A) set forth, in accordance with criteria established by the Secretary, a detailed survey of the local and State needs for the prevention and treatment of drug abuse and drug dependence, including a survey of the health facilities needed to provide services for drug abuse and drug dependence, and a plan for the development and distribution of such facilities and programs throughout the State in accordance with such needs;

(B) include in the survey conducted pursuant to subparagraph (A) an identification of the need for prevention and treatment of drug abuse and drug dependence by women and by individuals under the age of eighteen and provide assurance that prevention and treatment programs within the State will be designed to meet such need;

(6) provide for coordination of existing and planned treatment and rehabilitation programs and activities, particularly in urban centers;

(7) provide a scheme and methods of administration which will supplement, broaden, and complement State health plans developed under section 246(d)(2) of title 42;

(8) provide such methods of administration of the State plan, including methods relating to the establishment and maintenance of personnel standards on a merit basis (except that the Secretary shall exercise no authority with respect to the selection, tenure of office, or compensation of any individual employed in accordance with such methods), as are found by the Secretary to be necessary for the proper and efficient operation of the plan;

(9) provide that the State agency will make such reports, in such form and containing such information as the Secretary may from time to time reasonably require, and will keep such records and afford such access thereto as the Secretary may find necessary to assure the correctness and verification of such reports;

(10) provide that the State agency will from time to time, but not less often than annually, review its State plan and submit to the Secretary an analysis and evaluation of the effectiveness of the prevention and treatment programs and activities carried out under the plan, and any modifications in the plan which it considers necessary;

(11) provide reasonable assurance that Federal funds made available under this section for any period will be so used as to supplement and increase, to the extent feasible and practical, the level of State, local, and other non-Federal funds that would be in the absence of such Federal funds be made available for the programs described in this section, and will in no event supplant such State, local, and other non-Federal funds;

(12) provide reasonable assurances that treatment or rehabilitation projects or programs supported by funds made available under this section have provided to the State agency a proposed performance standard or standards to measure, or research protocol to determine, the effectiveness of such treatment or rehabilitation programs or projects; and

(13) contain such additional information and assurance as the Secretary may find necessary to carry out the provisions of this section.

(f) Approval by Secretary; alcoholism or mental health plan provisions; procedures for review of State plans

The Secretary shall approve any State plan and any modification thereof which complies with the provisions of subsection (e) of this section. A State plan submitted under subsection (e) of this section may also contain provisions relating to alcoholism or mental health. The Secretary, acting through the National Institute on Drug Abuse, shall establish procedures by which the National Institute on Drug Abuse shall review each State plan submitted pursuant to subsection (e) of this section and under which it shall complete its review of each such plan not later than September 15 of the calendar year in which the plan is submitted, or not later than sixty days after the plan is received by the National Institute on Drug Abuse, whichever is later.

(g) Payments; advances; reimbursements; installments

From the allotment of a State, the Secretary shall make grants to that State in accordance with this section. Payments under such grants may be made in advance or by way of reimbursement and in such installments as the Secretary may determine.

(Pub. L. 92-255, title IV, § 409, Mar. 21, 1972, 86 Stat. 80; Pub. L. 94-237, §§ 7, 8(a), 9(a)(1), (b)(1), Mar. 19, 1976, 90 Stat. 245-247; Pub. L. 94-371, § 10(a)(1), (b)(1), July 26, 1976, 90 Stat. 1040.)

AMENDMENTS

1976—Subsec. (a). Pub. L. 94-237, § 7, substituted $45,000,000 for each of the fiscal years ending June 30, 1975, and June 30, 1976, $11,250,000 for the period July 1, 1976, through September 30, 1976, and $45,000,000 for each of the fiscal years ending September 30, 1977, and September 30, 1978" for "and $45,000,000 for the fiscal year ending June 30, 1975".

Subsec. (c)(1)(A). Pub. L. 94-371, § 10(b)(1), substituted "a minimum allotment in excess of $100,000, multiplied by such fraction, the minimum allotment for such State may be increased by up to 50 percent in accordance with such demonstrated need" for "an allotment for a fiscal year in an amount not less than $150,000, the allotment for such State for such fiscal year may not be less than $150,000 multiplied by such fraction".

Pub. L. 94-237, § 8(a)(1), (2), redesignated subsec. (c)(1) as subsec. (c)(1)(A) and, as so redesignated,

added provision relating to the demonstration of a need for an allotment by a state determined in accordance with the methodology established under subsec. (c)(1)(B).

Subsec. (c)(1)(B). Pub. L. 94-237, § 8(a)(3), added subsec. (c)(1)(B).

Subsec. (e). Pub. L. 94-237, § 9(a)(1), added July contract deadline provision with reference to submission of plan to Secretary, added provision with respect to state plans which requires that each state plan to pertain to the twelve-month period commencing October 1 of the calandar year in which it is required to be submitted, added "in accordance with such need" at the end of par. (5) added par. (12), and redesignated former par. (12) as par. (13).

Subsec. (e)(5). Pub. L. 94-371, § 10(a)(1), designated existing provision as subpar. (A) and added subpar. (B).

Subsec. (f). Pub. L. 94-237, § 9(b)(1), added provisions relating to submission of state plans under subsec. (e) of this section with reference alcolholism and mental health and procedures for the review of plans by the Secretary through the National Institute on Drug Abuse.

EFFECTIVE DATE OF 1976 AMENDMENTS

Section 10(a)(2) of Pub. L. 94-371 provided that: "The amendment made by paragraph (1) [amending subsec. (e)(5) of this section] shall apply with respect to State plans submitted for grants under section 401 of the Drug Abuse Office and Treatment Act of 1972 [amending sections 2688a, 2688k, and 2688n-1 of Title 42, The Public Health and Welfare] after June 30, 1976."

Section 10(b)(2) of Pub. L. 94-371 provided that: "The amendment made by paragraph (1) [amending subsec. (c)(1)(A) of this section] shall apply with respect to allotments under section 409(c) of the Drug Abuse Office and Treatment Act of 1972 [subsec. (c) of this section] after June 30, 1976."

Section 9(a)(2) of Pub. L. 94-237 provided that: "The amendments made by paragraph (1) [amending subsec. (e) of this section] shall take effect January 1, 1976."

Section 9(b)(2) of Pub. L. 94-237 provided that: "The amendment made by paragraph (1) [amending subsec. (f) of this section] shall take effect January 1, 1976."

Section 8(b) of Pub. L. 94-237 provided that: "The amendments by subsection (a) of this section [amending subsec. (c) of this section] shall be effective with respect to fiscal years beginning on or after October 1, 1976."

PERIOD OF JULY 1, 1975, THROUGH SEPTEMBER 30, 1976, CONSIDERED AS ONE YEAR

Pub. L. 94-274, title II, § 206, Apr. 21, 1976, 90 Stat. 394, provided that: "The period of July 1, 1975, through September 30, 1976, shall be considered one year for the purposes of the following provisions of law—

"(1) sections 314(d)(2)(C)(ii) and (d)(3), 435,(b), 646, 1210, and 1315 of the Public Health Service Act (42 U.S.C. 246(d)(2)(C)(ii) and (d)(3), 289c-2(b), 291o-1, 300d-9, and 300e-14)

"(2) section 409(e) of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1176(e));

"(3) section 303 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4573);

"(4) sections 203(e)(1) and 237(a)(1)(C) of the Community Mental Health Centers Act (42 U.S.C. 2689b(e)(1) and 2689t(a)(1)(C)); and

"(5) section 205(b)(1) of the Water Pollution Control Act (33 U.S.C. 1285(b)(1))."

FISCAL YEAR TRANSITION PERIOD OF JULY 1, 1976, THROUGH SEPTEMBER 30, 1976, DEEMED PART OF FISCAL YEAR BEGINNING JULY 1, 1975

Fiscal year transition period of July 1, 1976, through Sept. 30, 1976, deemed part of fiscal year beginning July 1, 1975, for purposes of subsec. (c)(2) of this section, see Pub. L. 94-274, title II, § 204(8), Apr. 21, 1976, 90 Stat. 392, set out as a note under section 390e of Title 7, Agriculture.

CONTINUATION OF FEDERAL PROGRAMS AND ACTIVITIES DURING FISCAL YEAR TRANSITION PERIOD FROM JULY 1, 1976, THROUGH SEPTEMBER 30, 1976

Pub. L. 94-274, title I, § 115, Apr. 21, 1976, 90 Stat. 388, provided that:

"For the purposes of sections 409(b) and 409(c)(1) of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1176 (b) and (c)(1)), the period of July 1, 1976, through September 30, 1976, shall be considered a fiscal year and the exercise of authority pursuant to these provisions for that period shall be subject to the conditions stated in the following paragraphs:

"(1) notwithstanding the provision in section 409(b)(3)) [subsec. (b)(3) of this section], the limitation of $50,000 specified in section 409(b)(3) shall be decreased to $12,500 for that period; and

"(2) notwithstanding the provision in section 409(c)(1) [subsec. (c)(1) of this section], the amount of $100,000 specified in section 409(c)(1) shall be decreased to $25,000 for that period."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 1177, 1178 of this title; title 42 sections 300l-2, 3733.

§ 1177. Special project grants and contracts

(a) Scope of programs; priority

The Secretary shall—

(1) make grants to public and private nonprofit agencies, organizations, or institutions and enter into contracts with public and private agencies, organizations, institutions, and individuals to provide training seminars, educational programs, and technical assistance for the development of drug abuse prevention, treatment, and rehabilitation programs for employees in the private and public sectors;

(2) make grants to public and private nonprofit agencies, organizations, or institutions and enter into contracts with public and private agencies, organizations, and institutions to provide directly or through contractual arrangements for vocational rehabilitation counseling, education, and services for the benefit of persons in treatment programs and to encourage efforts by the private and public sectors of the economy to recruit, train, and employ participants in treatment programs;

(3) make grants to public and private nonprofit agencies, organizations, or institutions and enter into contracts with public and private agencies, organizations, institutions, and individuals to establish, conduct, and evaluate drug abuse prevention, treatment, and rehabilitation programs within State and local criminal justice systems;

(4) make grants to or contracts with groups composed of individuals representing a broad cross-section of medical, scientific, or social disciplines for the purpose of determining the causes of drug abuse in a particular area, prescribing methods for dealing with drug abuse in such an area, or conducting programs for dealing with drug abuse in such an area;

(5) make research grants to public and private nonprofit agencies, organizations, and institutions and enter into contracts with public and private agencies, organizations, and institutions, and individuals for improved drug maintenance techniques or programs; and

(6) make grants to public and private nonprofit agencies, organizations, and institutions and enter into contracts with public and private agencies, organizations, institutions, and individuals to establish, conduct, and evaluate drug abuse prevention and treatment programs.

In the implementation of his authority under this section, the Secretary shall accord a high priority to applications for grants or contracts for primary prevention programs. For purposes of the preceding sentence, primary prevention programs include programs designed to discourage persons from beginning drug abuse. To the extent that appropriations authorized under this section are used to fund treatment services, the Secretary shall not limit such funding to treatment for opiate abuse, but shall also provide support for treatment for non-opiate drug abuse including polydrug abuse.

(b) Authorization of appropriations

There are authorized to be appropriated $25,000,000 for the fiscal year ending June 30, 1972; $65,000,000 for the fiscal year ending June 30, 1973; $100,000,000 for the fiscal year ending June 30, 1974; $160,000,000 for each of the fiscal years ending June 30, 1975 and June 30, 1976; $40,000,000 for the period July 1, 1976, through September 30, 1976; and $160,000,000 for each of the fiscal years ending September 30, 1977, and September 30, 1978, to carry out this section.

(c) Coordination of applications for programs in a State; precedence restriction; project evaluation; application approval; criteria; proposed performance standards or research protocol

(1) In carrying out this section, the Secretary shall require coordination of all applications for programs in a State and shall not give precedence to public agencies over private agencies, institutions, and organizations, or to State agencies over local agencies.

(2) Each applicant within a State, upon filing its application with the Secretary for a grant or contract under this section, shall submit a copy of its application for review by the State agency (if any) designated or established under section 1176 of this title. Such State agency shall be given not more than thirty days from the date of receipt of the application to submit to the Secretary, in writing, an evaluation of the project set forth in the application. Such evaluation shall include comments on the relationship of the project to other projects pending and approved and to the State comprehensive plan for treatment and prevention of drug abuse under section 1176 of this title. The State shall furnish the applicant a copy of any such evaluation. A State if it so desires may, in writing, waive its rights under this paragraph.

(3) Approval of any application for a grant or contract under this section by the Secretary, including the earmarking of financial assistance for a program or project, may be granted only if the application substantially meets a set of criteria that—

(A) provide that the activities and services for which assistance under this section is sought will be substantially administered by or under the supervision of the applicant;

(B) provide for such methods of administration as are necessary for the proper and efficient operation of such programs or projects;

(C) provide for such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting for Federal funds paid to the applicant; and

(D) provide for reasonable assurance that Federal funds made available under this section for any period will be so used as to supplement and increase, to the extent feasible and practical, the level of State, local, and other non-Federal funds that would be in the absence of such Federal funds be made available for the programs described in this section, and will in no event supplant such State, local, and other non-Federal funds.

(4) Each applicant within a State, upon filing its application with the Secretary for a grant or contract to provide treatment or rehabilitation services shall provide a proposed performance standard or standards, to measure, or research protocol to determine, the effectiveness of such treatment or rehabilitation program or project.

(d) Programs and projects for women and juveniles; special consideration of applications

The Secretary shall give special consideration to applications under this section for programs and projects for prevention and treatment of drug abuse and drug dependence by women and for programs and projects for prevention and treatment of drug abuse and drug dependence by individuals under the age of eighteen.

(e) Payments; advances; reimbursement; installments

Payment under grants or contracts under this section may be made in advance or by way of reimbursement and in such installments as the Secretary may determine.

(Pub. L. 92-255, title IV, § 410, Mar. 21, 1972, 86 Stat. 82; Pub. L. 94-237, §§ 10, 11, Mar. 19, 1976, 90 Stat. 247; Pub. L. 94-371, § 10(c)(1), July 26, 1976, 90 Stat. 1040.)

AMENDMENTS

1976—Subsec. (a). Pub. L. 94-237, § 10(a), added provisions which authorized the Secretary to give a high priority to applications for grants and contracts for primary prevention programs, and set forth programs included within primary prevention programs and the scope of the Secretary's funding authority.

Subsec. (b). Pub. L. 94-237, § 11, substituted "$160,000,000 for each of the fiscal years ending June 30, 1975 and June 30, 1976; $40,000,000 for the period July 1, 1976, through September 30, 1976; and $160,000,000 for each of the fiscal years ending September 30, 1977, and September 30, 1978," for "and $160,000,000 for the fiscal year ending June 30, 1975,".

Subsec. (c)(4). Pub. L. 94-237, § 10(b), added subsec. (c)(4).

Subsec. (d). Pub. L. 94-371 added subsec. (d). Former subsec. (d) redesignated (e).

Subsec. (e). Pub. L. 94-371 redesignated former subsec. (d) as (e).

EFFECTIVE DATE OF 1976 AMENDMENT

Section 10(c)(2) of Pub. L. 94-371 provided that: "The amendment made by paragraph (1) [amending subsecs. (d) and (e) of this section] shall apply with respect to applications submitted for grants or contracts under section 410 of the Drug Abuse Office and Treatment Act of 1972 [this section] after June 30, 1976."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 1178 of this title; title 42 section 300*l*-2.

§ 1178. Records and audit

(a) Assistance records; contents

Each recipient of assistance under section 1176 or 1177 of this title pursuant to grants or contracts entered into under other than competitive bidding procedures shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant or contract, the total cost of the project or undertaking in connection with which such grant or contract is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(b) Access to pertinent information for audit and examination

The Secretary and Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients that are pertinent to such grants or contracts.

(Pub. L. 92-255, title IV, § 411, Mar. 21, 1972, 86 Stat. 83.)

§ 1179. National Drug Abuse Training Center

(a) Establishment; functions; general policies; transfer of supervision

The Director shall establish a National Drug Abuse Training Center (hereinafter in this section referred to as the "Center") to develop, conduct, and support a full range of training programs relating to drug abuse prevention functions. The Director shall consult with the National Advisory Council for Drug Abuse Prevention regarding the general policies of the Center. The Director may supervise the operation of the Center initially, but shall transfer the supervision of the operation of the Center to the National Institute on Drug Abuse not later than December 31, 1974.

(b) Activities and material

The Center shall conduct or arrange for training programs, seminars, meetings, conferences, and other related activities, including the furnishing of training and educational materials for use by others.

(c) Persons eligible for services and facilities

The services and facilities of the Center shall, in accordance with regulations prescribed by the Director, be available to (1) Federal, State, and local governmental officials, and their respective staffs, (2) medical and paramedical personnel, and educators, and (3) other persons, including drug dependent persons, requiring training or education in drug abuse prevention.

(d) Authorization of appropriations; fiscal year availability

(1) For the purpose of carrying out this section, there are authorized to be appropriated $1,000,000 for the fiscal year ending June 30, 1972, $3,000,000 for the fiscal year ending June 30, 1973, $5,000,000 for the fiscal year ending June 30, 1974, and $6,000,000 for the fiscal year ending June 30, 1975.

(2) Sums appropriated under this subsection shall remain available for obligation or expenditure in the fiscal year for which appropriated and in the fiscal year next following.

(Pub. L. 92-255, title IV, § 412, Mar. 21, 1972, 86 Stat. 84.)

NATIONAL ADVISORY COUNCIL FOR DRUG ABUSE PREVENTION

Section 1151 of this title, which established the National Advisory Council for Drug Abuse Prevention, was repealed by Pub. L. 92-255, title I, § 104, Mar. 21, 1972, 86 Stat. 67, eff. June 30, 1975.

FISCAL YEAR TRANSITION PERIOD OF JULY 1, 1976, THROUGH SEPTEMBER 30, 1976, DEEMED PART OF FISCAL YEAR BEGINNING JULY 1, 1975

Fiscal year transition period of July 1, 1976, through Sept. 30, 1976, deemed part of fiscal year beginning July 1, 1975, for purposes of subsec. (d)(2) of this section, see Pub. L. 94-274, title II, § 204(8), Apr. 21, 1976, 90 Stat. 392, set out as a note under section 390e of Title 7, Agriculture.

§ 1180. Drug abuse among Federal civilian employees

(a) Civil Service Commission responsibility for policies and services; use of existing governmental facilities

The Civil Service Commission shall be responsible for developing and maintaining, in cooperation with the Director and with other Federal agencies and departments, appropriate prevention, treatment, and rehabilitation programs and services for drug abuse among Federal civilian employees. Such policies and services shall make optimal use of existing governmental facilities, services, and skills.

(b) Similar programs and services in non-Federal government and private industry

The Director shall foster similar drug abuse prevention, treatment, and rehabilitation programs and services in State and local governments and in private industry.

(c) Disqualification solely on ground of prior drug abuse prohibited; certain agencies, national security employment, and sensitive positions excepted from restriction

(1) No person may be denied or deprived of Federal civilian employment or a Federal profession or other license or right solely on the ground of prior drug abuse.

(2) This subsection shall not apply to employment (A) in the Central Intelligence Agency, the Federal Bureau of Investigation, the National Security Agency, or any other department or agency of the Federal Government designated for purposes of national security by the President, or (B) in any position in any department or agency of the Federal Government, not referred to in clause (A), which position is determined pursuant to regulations prescribed by the head of such department or agency to be a sensitive position.

(d) Dismissal for functional disability

This section shall not be construed to prohibit the dismissal from employment of a Federal civilian employe who cannot properly function in his employment.

(Pub. L. 92-255, title IV, § 413, Mar. 21, 1972, 86 Stat. 84.)

SUBCHAPTER V—NATIONAL INSTITUTE ON DRUG ABUSE

§ 1191. Administration of programs

(a) Establishment of the National Institute on Drug Abuse; functions; drug abuse prevention, treatment, and rehabilitation programs

There is established the National Institute on Drug Abuse (hereinafter in this subchapter referred to as the "Institute") to administer the programs and authorities of the Secretary of Health, Education, and Welfare (hereinafter in this subchapter referred to as the "Secretary") with respect to drug abuse prevention functions. The Secretary, acting through the Institute, shall, in carrying out the purpose of sections 241, 242, and 242a of title 42 with respect to drug abuse, develop and conduct comprehensive health, education, training, research, and planning programs for the prevention and treatment of drug abuse and for the rehabilitation of drug abusers. The Secretary shall carry out through the Institute the administrative and financial management, policy development and planning, evaluation, and public information functions which are required for the implementation of such programs and authorities.

(b) Appointment of Director and employment and function of officers and employees of Institute

(1) The Institute shall be under the direction of a Director (hereinafter in this subchapter referred to as the "Director") who shall be appointed by the Secretary.

(2) The Director, with the approval of the Secretary, may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to administer the programs and authorities to be carried out through the Insitute.

(c) Participation of certain related disciplines in programs of Institute

The programs of the Institute shall be administered so as to encourage the broadest possible participation of professionals and paraprofessionals in the fields of medicine, science, the social sciences, and other related disciplines.

(Pub. L. 92-255, title V, § 501, Mar. 21, 1972, 86 Stat. 85; Pub. L. 93-282, title II, § 204, May 14, 1974, 88 Stat. 136; Pub. L. 94-237, § 12(a), Mar. 19, 1976, 90 Stat. 247.)

AMENDMENTS

1976—Subsec. (a). Pub. L. 94-237, § 12(a)(1), substituted "subchapter" for "section" whenever appearing therein.

Subsec. (b)(1). Pub. L. 94-237, § 12(a)(2), inserted "(hereinafter in this subchapter referred to as the 'Director')" following "Director".

1974—Subsec. (a). Pub. L. 93-282 deleted provisions for establishment of the Institute effective Dec. 31, 1974, and for such establishment in the National Institute of Mental Health, inserted references to sections 242 and 242a of Title 42, and required the Secretary to carry out through the Institute the administrative and financial management, policy development and planning, evaluation, and public information functions required for implementation of prescribed programs and authorities.

Subsec. (b). Pub. L. 93-282 designated existing provisions as par. (1) and added par. (2).

§ 1192. Coordination, information, assistance and assignment activities and services

(a) Coordination of prevention functions; central clearinghouse for information and assistance

The Director shall—

(1) coordinate or assure coordination of Federal drug abuse prevention functions with corresponding functions of State and local governments; and

(2) provide for a central clearinghouse for Federal, State, and local governments, public and private agencies, and individuals seeking drug abuse information and assistance from the Federal Government.

(b) Technical assistance to State and local agencies; local programs for analysis and resolutions; conferences, expenses; model legislation; uniform procedures, criteria and forms

In carrying out his functions under this section, the Director may—

(1) provide technical assistance—including advice and consultation relating to local programs, technical and professional assistance, and, where deemed necessary, use of task forces of public officials or other persons assigned to work with State and local governments—to analyze and identify State and local drug abuse problems and assist in the development of plans and programs to meet the problems so identified;

(2) convene conferences of State, local, and Federal officials, and such other persons as the Director shall designate, to promote the purposes of this chapter, and the Director is authorized to pay reasonable expenses of individuals incurred in connection with their participation in such conferences; and

(3) draft and make available to State and local governments model legislation with respect to State and local drug abuse programs and activities, and provide for uniform forms for, procedures for the submission of, and criteria for the consideration of applications of State and local governments and individuals for grants and contracts for drug abuse control and treatment programs.

(c) Task forces

In implementation of his authority under subsection (b)(1) of this section, the Director may—

(1) take such action as may be necessary to request the assignment, with or without reimbursement, of any individual employed by any Federal department or agency and engaged in any Federal drug abuse prevention function or drug traffic prevention function to serve as a member of any such task force; except that no such person shall be so assigned during any one fiscal year for more than an aggregate of ninety days without the express approval of the head of the Federal department or agency with respect to which he was so employed prior to such assignment;

(2) assign any person employed by the Institute to serve as a member of any such task force or to coordinate management of such task forces; and

(3) enter into contracts or other agreements with any person or organization to serve on or work with such task forces.

(Pub. L. 92-255, title V, § 502, as added Pub. L. 94-237, § 12(b)(1), Mar. 19, 1976, 90 Stat. 247.)

REFERENCES IN TEXT

This chapter, referred to in subsec. (b), was in the original, this Act, meaning Pub. L. 92-255, Mar. 21, 1972, 86 Stat. 65, known as the Drug Abuse Office and Treatment Act of 1972, which enacted this chapter, and amended sections 5313, 5315, and 5316 of Title 5, Government Organization and Employees, and sections 218, 246, 257, 2684, 2688a, 2688k, 2688n-1, and 2688t of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note under section 1101 of this title and Tables volume.

PRIOR PROVISIONS

A prior section 502 of Pub. L. 92-255, Mar. 21, 1972, 86 Stat. 85, amended section 217 of the Public Health Service Act by adding subsec. (e) [section 218(e) of Title 42, The Public Health and Welfare], and amended section 266 of the Community Mental Health Centers Act [former section 2688t of Title 42, The Public Health and Welfare].

§ 1193. Research and development: encouragement; clinical research facilities: establishment; authorization of appropriations

(a) The Director shall encourage and promote (by grants, contracts, or otherwise) expanded research programs to create, develop, and test—

(1) synthetic analgesics, antitussives, and other drugs which are—

(A) nonaddictive, or

(B) less addictive than opium or its derivatives, to replace opium and its derivatives in medical use;

(2) long-lasting, nonaddictive blocking or antagonistic drugs or other pharmacological substances for treatment of heroin addiction; and

(3) detoxification agents which, when administered, will ease the physical effects of withdrawal from heroin addiction.

In carrying out this section the Director is authorized to establish, or provide for the establishment of, clinical research facilities.

(b) For purposes of carrying out subsection (a) of this section there are authorized to be appropriated $7,000,000 for the fiscal year ending June 30, 1976, $1,750,000 for the period July 1, 1976, through September 30, 1976, $7,000,000 for the fiscal year ending September 30, 1977, and $7,000,000 for the fiscal year ending September 30, 1978.

(Pub. L. 92-255, title V, § 503, as added Pub. L. 94-237, § 13(a), Mar. 19, 1976, 90 Stat. 248.)